THE SALK INSTITUTE - GOVERNMENT SERVICES DIVISION (TSI-GSD)

ENVIRONMENTAL ASSESSMENT (FINAL)

Prepared For

Headquarters
U.S. Army Medical Research and Development Command
Fort Detrick, Frederick, Maryland

Prepared By:

U.S. Army Medical Materiel Development Activity
Fort Detrick, Frederick, Maryland
with Technical Assistance from
Telemarc, Inc.
Fairfax, Virginia

Contract No. DAMD17-91-D-1006

August 14, 1992

DEPARTMENT OF THE ARMY
U.S. Army Medical Research and Development Command
U.S. Army Medical Materiel Development Activity
Fort Detrick, Frederick, MD 21702-5012

ENVIRONMENTAL ASSESSMENT

Operation of The Salk Institute-Government Services Division

August 1992

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EXECUTIVE SUMMARY

This Environmental Assessment, *The Salk Institute - Government Services Division (TSI-GSD) Environmental Assessment,* was researched and prepared by the U.S. Army Medical Materiel Development Activity with technical assistance by Telemarc,, Inc., Fairfax, Virginia, under Contract DAMD17-91-D-1006 to the U.S. Army Medical Research and Development Command (USAMRDC). The Salk Institute - Government Services Division (TSI-GSD), located in Swiftwater, Monroe County, Pennsylvania, is a division of The Salk Institute, La Jolla, California, a private, not-for-profit organization. It is not an agency or activity of the U.S. Government. Work at TSI-GSD is performed under a contract with USAMRDC. This work is performed to produce vaccines and diagnostic reagents for the protection of military personnel and requires additional, related activities in support of these primary efforts.

This assessment was prepared in accordance with the guidance provided in Army Regulation 200-2 (32 CFR Part 651), adheres to the requirements set forth in the National Environmental Policy Act (NEPA), and maximizes previous work accomplished during preparation of the Final Programmatic Environmental Impact Statement on the Biological Defense Research Program.

The assessment systematically renews the nature of the activities conducted at TSI-GSD, the internal environment, the associated risks and issues, and the security and safety of operations. Particular attention is given to accident and emergency procedures as well as to certain special considerations associated with the operations of TSI-GSD.

TSI-GSD is then reviewed in considerable detail within the context of the surrounding environment and socioeconomic setting. Feasible alternatives with regard to needs of the United States and the Army and potential adverse effects on the environment are evaluated.

Principal conclusions of the assessment are: (1) routine operation is safe and poses no significant threat to the environment; (2) risks to the environment associated with accidental release of dangerous substances or hazardous organisms are extremely small; and therefore (3) continuing operation of TSI-GSD in its present scope will have no significant adverse environmental impact and will result in significant benefits to the United States. Thus, the Environmental Assessment leads to a Finding of No Significant Impact.

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1.0 PURPOSE AND NEED FOR PROPOSED ACTION

1.1 Introduction

In 1989, the Department of Defense (DoD) prepared a Final Programmatic Environmental Impact Statement (FPEIS) on the environmental effects related to the Biological Defense Research Program (BDRP). The Record of Decision (ROD) indicated that although certain aspects of the program remain controversial, particularly relative to aerosol testing and use of genetically engineered microorganisms (GEMs), the program remains unaltered because the environmental analysis found no evidence of significant negative environmental impacts (Appendix A). Those specific BDRP sites examined in the FPEIS,, to include The Salk Institute-Government Services Division (TSI-GSD),), were in compliance with applicable-environmental standards, including local, state, and federal regulations and guidelines (BDRP, 1989).

The BDRP was established to provide physical and medical strategies for the defense of military personnel and equipment against the use of biological weapons. The BDRP is a research, development, test and evaluation (RDT&E) program funded by Congress and implemented through DoD by the Army. The program involves several Department of the Army (DA) commands including the U.S. Army Medical Research and Development Command (USAMRDC). The BDRP develops protection, treatment, detection and decontamination procedures against biological warfare agents. The USAMRDC executes the Army Medical RDT&E program. TSI-GSD supports the Army Medical Military Disease Hazards and Medical Biological Defense RDT&E program which includes developing medical countermeasures (e.g., protection, diagnosis and treatment) against diseases of military importance found naturally throughout the world (the Infectious Disease Research Program, IDRP) as well as against biological warfare agents (BDRP) by providing vaccines and diagnostic reagents and by conducting related supporting activities to these primary tasks.

Various public and government groups were involved with the preparation and completion of the BDRP FPEIS. The resulting dialogues from these meetings and multidisciplinary, multidimensional analyses indicated that public concerns expressed at the local level were programmatic in nature, and not directly related to specific sites within the BDRP. The FPEIS found that any adverse impacts associated with continuation of BDRP research efforts were minimal.

The objective of this Environmental Assessment (EA) is to evaluate the environmental impacts of TSI-GSD. TSI-GSD is one of approximately 50 sites of program execution of the BDRP. TSI-GSD is a subsidiary of The Salk Institute, La Jolla, California, a private, not-for-profit organization, and is not a government organization. Work at TSI is performed under a contract with USAMRDC. This work is performed to produce vaccines and diagnostic reagents for the U.S. Army and includes scale-up and associated activities in support of vaccine production.

Army Regulation (AR) 200-2 (32 CFR Part 651) provides guidance for preparation of EAs for Army actions, including adherence to requirements set forth in the National Environmental Policy Act (NEPA) and implementing regulations. To reduce redundancy with previous relevant documents and as required by the Council on Environmental Quality (CEQ) (40 CFR Parts 1500-1508), this EA is tiered to the BDRP FPEIS. This approach entails referencing specific analyses, discussions and conclusions of that document without providing detailed discussions in the present report. However, the most relevant sections of the FPEIS describing environmental consequences associated with operations of TSI-GSD and Ask/issue categories are incorporated into the Appendices of the present document Since the BDRP and IDRP apply parallel methods and safety/containment procedures, BDRP FPEIS assumptions and conclusions apply equally to the IDRP. That is, environmental effects are determined by the risks associated with the actual work and not by the source of funding for the work. This approach is consistent with AR-200-2 (Section 2-6c) and the Council on Environmental Quality (CEQ) regulations [40 CFR Parts 1502.20, 1502.4(d), 1508.28(a)].

1.2 Description of the Proposed Action

The proposed action is continuance of operations at the TSI-GSD. TSI-GSD provides support to the medical RDT&E mission including both the BDRP and IDRP and produces:

(1) vaccines and

(2) test reagents for diagnosing diseases (diagnostics).

TSI-GSD currently produces vaccines using genetically engineered microorganisms (GEMs) developed elsewhere. These include vaccinia-vectored vaccines and a recombinant *Escherichia coli-Shigella flexneri* vaccine. Additional studies with a recombinant insect virus strain (baculovirus) for development of a new anthrax vaccine are in progress.

1.3 Public Evaluation

TSI-GSD was evaluated in a programmatic context in the BDRP FPEIS and determined not to cause any significant negative impacts to the environment. In this EA,, TSI-GSD is analyzed on a site-specific basis to determine whether the continued operation of the facility may significantly affect the environment. This EA also identifies alternatives to continuing the USAMRDC contract with TSI-GSD and evaluates cumulative impacts of TSI-GSD operations.

2.0 DESCRIPTION OF THE SALK INSTITUTE - GOVERNMENT SERVICES DIVISION (TSI-GSD)

2.1 Location and Facilities

TSI-GSD is located on U.S. Route 611 in Swiftwater, Monroe County, Pennsylvania. The general location of TSI-GSD is given in Figures 2-1 and 2-2. Pocono Township exercises municipal jurisdiction over this area. The character of the area is largely rural although some tourist activity occurs along Route 611. TSI-GSD is located on slightly more than nine acres of land and consists of four buildings. TSI-GSD is housed in a single-use complex which was built in 1962 expressly for its current use. The first expansion was completed in December 1983. A second expansion was completed in 1990. A detailed schematic of TSI-GSD is provided in Figure 2-3.

The facility adjoins the property of Connaught Laboratories, Inc. on the north and east. Connaught Laboratories is engaged in biomedical research and production of vaccines for the following diseases: tetanus, influenza, diphtheria and pertussis. Production of vaccines has been conducted at the site occupied by TSI-GSD and Connaught Laboratories since the 1890s (Slee Laboratories). Other vaccine production entities at this location have included National Drug Company and Merrell National Laboratories. The current TSI-GSD facility was donated to The Salk Institute for Biological Studies by Richardson-Merrell, Inc. (now known as Richardson-Vick, Inc.) in 1978.

2.2 Production Activities and Risk/Issue Categories

2.2.1 Production Activities

TSI-GSD provides support, under USAMRDC contract, to the BDRP and IDRP through the preparation of vaccines and diagnostic materials. All of the production activities conducted at TSI-GSD are financed by USAMRDC.

Viral, rickettsial, and bacterial vaccines are produced as needed for evaluation in laboratory animal models and use in humans. TSI-GSD manufactures vaccines, tests them for safety and efficacy in animals and conformance to other criteria specified by the Food and Drug Administration (FDA), bottles, and stores the product. Production of some of the vaccines requires the use a pathogenic strain of organism (e.g., Q fever) as starting (seed) material. Others are produced from live, attenuated strains of organisms which are not virulent. Organisms (attenuated or native strain) which may be found at TSI-GSD include vaccinia virus, *Escherichia coli-Shigella flexneri*, Chikungunya, Western equine encephalitis, Eastern equine encephalitis, Venezuelan equine encephalomyelitis, Rift Valley fever, and Junin viruses; *Coxiella burnetii* (Q fever) rickettsia and *Francisella tularensis* (tularemia) bacteria The only strain of Junin virus used at TSI-GSD is a low-virulence laboratory strain

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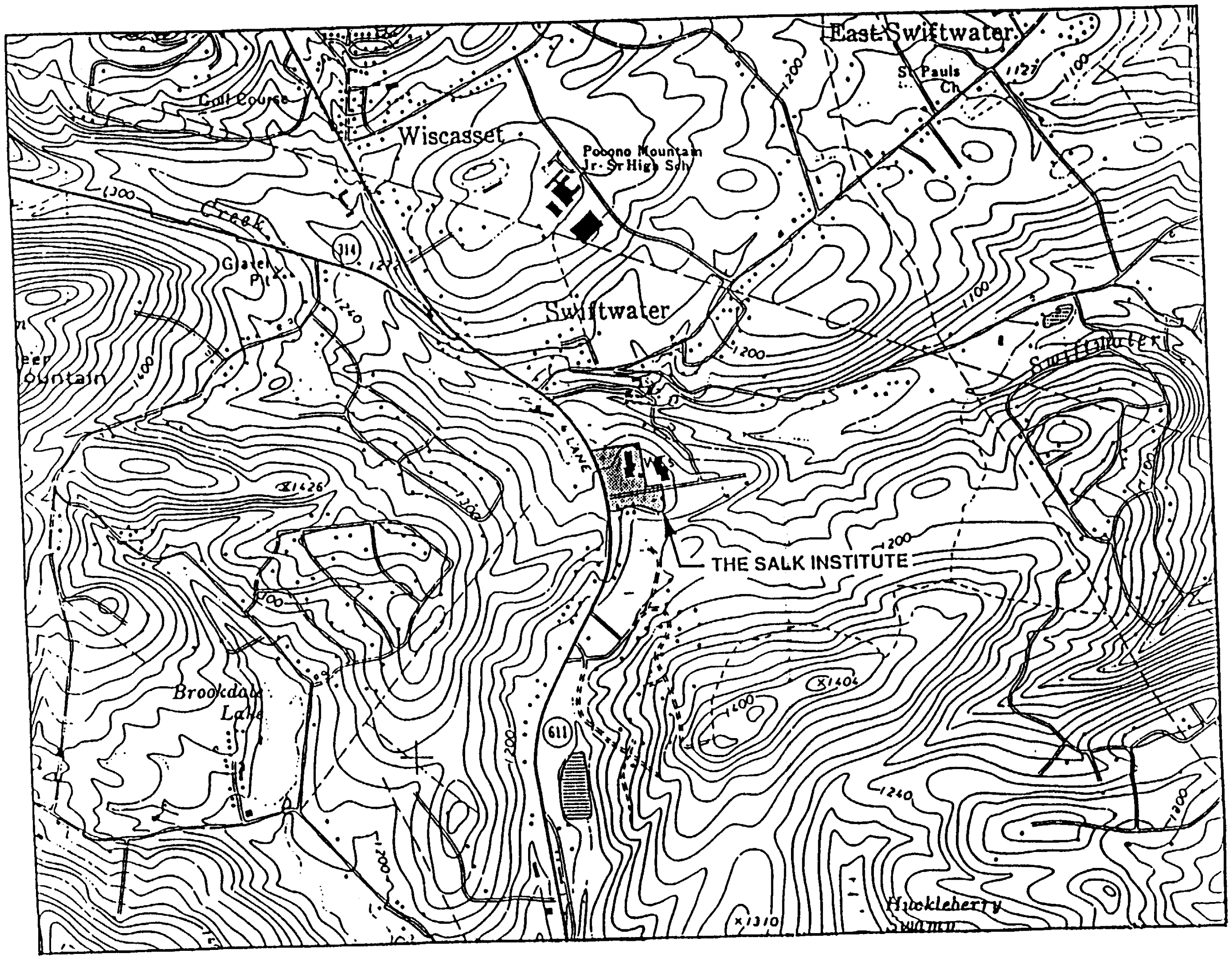

Figure 2-1 Location of TSI-GSD

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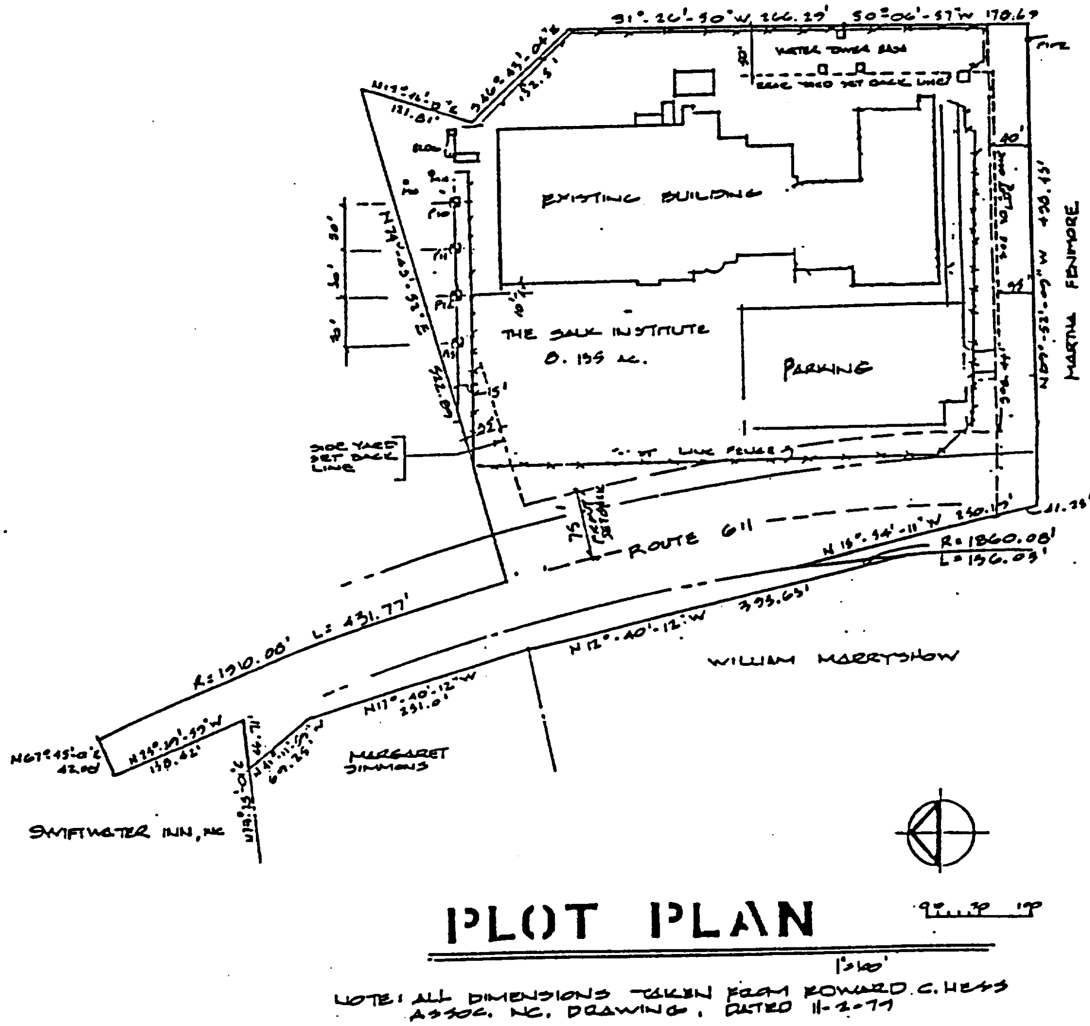

Figure 2-2 Layout of TSI-GSD Property

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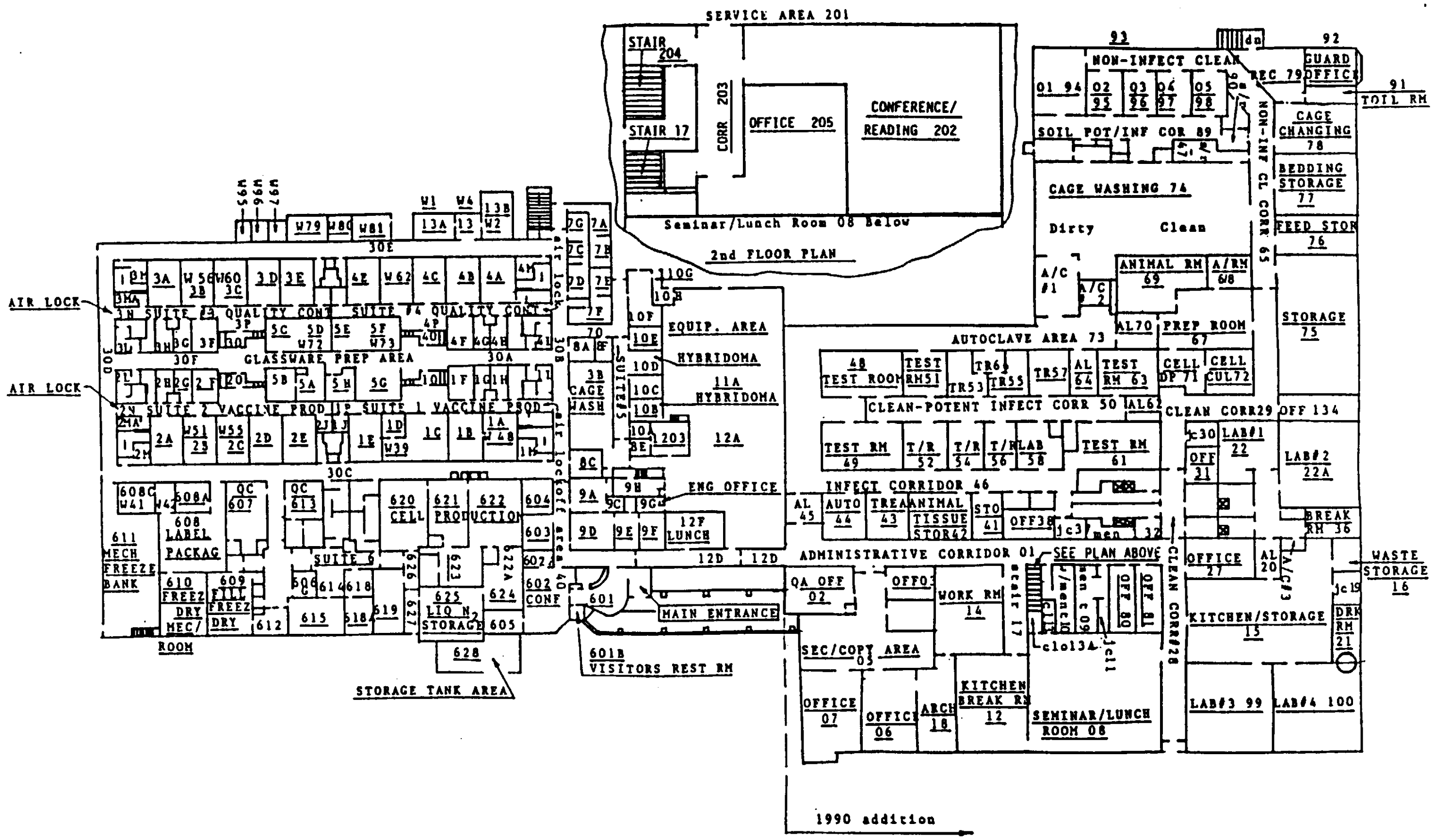

Figure 2-3 Floor Plan of TSI-GSD

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that is used as a vaccine. Production of these biomedical products is accomplished using inactivated and attenuated biological agents. Inactivated products are infectious agents which are grown, harvested, killed (inactivated), and stored. Attenuated agents are infectious but do not normally produce symptoms of disease. These latter agents are grown, harvested, and frozen for storage prior to use in manufacturing vaccine.

2.2.2 Purpose of TSI-GSD

TSI-GSD develops and produces vaccines for USAMRDC. These are used by the DoD to protect at-risk personnel including military personnel potentially exposed to hostile use of biological warfare against them (BDRP); those who may be deployed in environments containing native infectious microbiological agents (IDRP); laboratory workers; and to deter, as well as to constrain, U.S. adversaries from producing biological warfare agents.

2.2.3 Risk/Issue Categories

The BDRP FPEIS identified TSI-GSD as conducting work in Risk/Issue categories I and VI (high hazard organisms and vaccine and drug therapy development) (see Appendix 3, BDRP FPEIS). Risk/Issue categories correspond, in part, to Biosafety Levels (BLs). Biosafety levels describe the combinations of laboratory techniques, safety equipment and laboratory facilities necessary to reduce or eliminate the potential hazards posed by working with infectious agents to laboratory personnel and to the environment. The maximum biosafety level utilized at TSI-GSD is based on prior laboratory experience, disease transmissibility, pathogenicity and availability of vaccines or treatments. After evaluating these characteristics for a large group of organisms, the Centers for Disease Control (CDC) and the Subcommittee on Arbovirus Laboratory Safety (SALS) of the American Society of Tropical Medicine and Hygiene have determined a BL categorization for all potentially infectious and/or disease-causing microorganisms. TSI-GSD does not use organisms with a hazard classification greater than BL-3 (CC, 1988). Thus, these organisms are associated with the Risk/Issue category *High Hazard Organisms* (see Appendix B).

2.3 Security and Sextets

2.3.1 Building Security

TSI-GSD is located on a fenced 9.13 acre lot. Access to the facility and grounds is restricted to two controlled-access gates. Guards are stationed at the gates during working hours. After hours when the gates and building are locked, guards patrol the grounds. Employees must have identification badges and visitors are escorted. A computer card-key system limits access during non-duty hours. All entries are recorded. Video cameras monitor areas in the building where visual inspection is not possible. Surveillance of the grounds and buildings occurs on a 24 hour a day basis.

The Security at includes a detailed security risk analysis, vulnerability and threat assessment, detection devices, site plan, and Standard Operating Procedures (SOPs). These procedures for the Security Program are retained by the supervisor of the guard force.

2.3.2 Safety

Work in the laboratory conforms to the guidelines established in the publication, *Biosafety in Microbiological and Biomedical Laboratories* Centers for Disease Control and National Institutes of Health, 1988, DHHS Publ. No. (CDC) 88-8395 (CDC,, 1988). Detailed descriptions and procedures for biosafety may be found in that publication and in Section 2.3.2.1.

The Safety Program is managed in accordance with AR 385-69 (see 32-CFR Part 626, Biological Defense Safety Program, Federal Register, Vol. 57, No. 64, April 2, 1992). A Biological Safety Program, developed by TSI-GSD, has been implemented to provide work place safety and health for employees, visitors, and protection to the environment. It includes safety management and responsibilities, personnel training, personal protective clothing and equipment, waste handling procedures, inspections, hazard communication, laboratory training, and several other program elements. This document is available from the safety officer.

A hazard analysis, to determine safety precautions, personnel protection, engineering features, and procedures to prevent exposure has been performed for each operation. Specialized SOPs, which include safety, personal protective clothing and equipment, and spill clean-up procedures, have been developed for each protocol using information from the analysis. A copy of the SOP is kept by the Principal Investigator (PI) for each protocol.

Requirements of the Hazard Communication Standard, 29 CFR 1910.1200 and Laboratory Standard, 29 CFR 1910.1450 have been met. Employees are knowledgeable of laboratory hazard information. For reference, material safety data sheets are available at all times in the Safety Office. Supervisors and/or PIs are responsible for ensuring the safe operations of the laboratory and enforcement of safe practices of employees.

2.3.2.1 Special Procedures

Work with infectious material is conducted in laboratories which provide the appropriate level of containment relative to the risk. The various combinations of laboratory practices and protocols, laboratory facilities, safety equipment and facility engineering describe the BE of a laboratory. Recommendations for BLs for particular infectious agents are determined based on the potential hazard associated with activities involving that organism. TSI-GSD is classified as a BL-3 facility based on these criteria. General characteristics (DHHS Pub. No. (CDC) 88-8395) of a BL-3 laboratory include:

laboratory has special engineering features which make it possible for laboratory workers to handle hazardous materials without endangering themselves, the community, or the environment.......The unique features which distinguish this laboratory from the basic laboratory are the provisions for access control and a specialized ventilation systems...... In all cases, the laboratory is separated by a controlled access zone from areas open to the public (CDC, 1988).

Specific features of a BL-3 laboratory include:

A. Standard Microbiological Practices

1. Work surfaces are decontaminated at least once a day and after any spill of viable material.

2. All infectious liquid or solid wastes are decontaminated before disposal.

3. Mechanical pipetting devices are used; mouth pipetting is prohibited.

4. Eating, drinking, smoking, storing food and applying cosmetics are not permitted in the work area

5. Persons wash their hands after handling infectious materials and animals when they leave the laboratory

6. All procedures are performed carefully to minimize the creation of aerosols.

B. Special Practices

1. Laboratory doors are kept closed when experiments are in progress.

2. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak proof container which is closed before being removed from the laboratory.

3. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support services. Persons who are at increased risk of acquiring infection or for whom infection my be unusually hazardous are not allowed in the laboratory or animal rooms. The director has final responsibility for assessing each circumstance and determining who may enter or work in the laboratory

4. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g. immunization), and who comply with all entry and exit procedures enter the laboratory of animal rooms.

5. When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies any special requirements for entering the laboratory such as the need for immunizations, respirators, or other personal protective measures.

6. All activities involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.

7. The work surfaces of biological safety cabinets and other containment equipment are decontaminated when work with infectious materials is finished. Plastic-baked paper toweling used on nonperforated work surfaces within biological safety cabinets facilitates clean-up.

8. An insect and rodent control program is in effect.

9. Laboratory clothing that protects street clothing (e.g. solid front or wrap-around gowns, scrub suits, coveralls) is worn in the laboratory. Laboratory clothing is not worn outside the laboratory, and it is decontaminated before being laundered.

10. Special care is taken to avoid skin contamination with infectious materials; gloves should be worn when handling infected animals and when skin contact with infectious materials is unavoidable.

11. Molded surgical masks or respirators are worn in rooms containing infected animals.

12. Animals and plants not related to the work being conducted are not permitted in the laboratory.

13. AN wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

14. Vacuum lines are protected with *high* efficiency particulate air (HEPA) filters and liquid disinfectant traps.

15. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of infectious fluids. extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the sheath or guard or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

16. Spills and accidents which result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation surveillance, and treatment are provided and written records are maintained.

17. Baseline serum samples for all laboratory and other at-risk personnel should be collected periodically, depending on the agents handled or the function of the laboratory.

18. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to need instructions on practices and procedures and procedures to follow them.

C. Containment Equipment

Biological safety cabinets or other appropriate combinations of personal protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge safety caps, sealed centrifuge rotors, and containment caging for animals) are used for all activities with infectious materials which pose a threat of aerosol exposure. These include: manipulation of cultures and of those clinical or environmental materials which may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids infected animals and eggs, and of infected animals and embryonated eggs, and necropsy of infected animals.

D. Laboratory Facilities

1. The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories or activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the laboratory.

2. The interior surface of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being scaled to facilitate decontaminating the area.

3. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

4. Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are Trouble for cleaning.

5. Each laboratory contains a sink for handwashing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.

6. Windows in the laboratory are closed and sealed.

7. Access doors to the laboratory or containment module are self closing.

8. An autoclave for decontaminating laboratory wastes is available, preferably within the laboratory.

9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry areas. The exhaust air is not recirculated to any other area of the building, is discharged to the outside, and is dispersed away from occupied areas and air intakes. Personnel must verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room can be discharged to the outside without being filtered or otherwise treated.

10. The HEPA-filtered exhaust air from Class I or Mass II biological safety cabinets is discharged directly to the outside or through the building exhaust system. Exhaust air from Class I or II biological safety cabinets my be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months. If the HEPA-filtered exhaust air from class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system (CHIC, 1988).

In addition to these minimum BL-3 guidelines, laboratory personnel at TSI-GSD shower prior to entering and exiting laboratories during production of products intended for human use or when using seed material.

Infectious organisms (seed material) are manipulated only in biological safety cabinets. The safety cabinets are certified by the TSI-GSD Quality Assurance Unit when installed, on an annual basis or if they are relocated within the premises by trained TSI-GSD personnel. Used cabinet filters are decontaminated with formaldehyde vapor prior to disposal. Final exhaust from the laboratory is discharged through a stack elevated 35 feet above the roof of the building.

There are four 3,200 square foot and one 360 square foot BL-3 containment laboratories at TSI-GSD. There are also 1,300 square feet of Research & Development laboratories and a 6,800 square foot BL-3 animal test facility at TSI-GSD. The floors, walls, and ceilings of the BL-3 laboratories and animal facilities are constructed of non-permeable concrete. All utility/ventilation connections to these BL-3 suites are embedded in sealed concrete. Access to the BL-3 suites is through a pass-through box equipped with ultraviolet disinfection lights and an ultraviolet air lock. Male and female access change rooms with door interlocks are used by production personnel prior to entering or leaving the suite.

2.3.2.2 Waste Stream Management

Wastewater potentially containing infectious material, including viruses, is sterilized prior to leaving the facility. All wastewater from TSI-GSD laboratories enters one of three 5,000 gallon holding tanks and then undergoes decontamination by heat-treatment. When the capacity of the tanks reaches 3,500 gallons an annunciation alarm sounds. The sterilization procedure is then initiated manually. This procedure entails an automated process of steam heating the contents to 226 degrees Fahrenheit for a minimum of six hours. The holding tanks are designed so that wastewater cannot be discharged unless the sterilization cycle is complete. Although culturing for the presence of microorganisms is not performed on the wastewater after the sterilization cycle is complete, maintenance of these temperatures and time requirements has been shown to be more than sufficient to render the effluent sterile of infectious agents (Block, 1983). After this sterilization procedure, the resulting effluent wastewater from TSI-GSD undergoes additional treatment at the wastewater treatment plant of Connaught Laboratories located on property adjacent to TSI-. Non-laboratory wastewater from TSI-GSD facility is discharged to the Connaught Laboratories wastewater treatment facility via a separate sanitary sewer connection. The effluent is then discharged into Swiftwater Creek.

The Connaught Laboratory treatment facility has a National Pollutant Discharge Elimination System (NPDES) permit from the Commonwealth of Pennsylvania Compliance with the terms of this permit requires sampling and measurement of particular characteristics of the wastewater stream. Once the wastewater from Connaught Laboratories/TSI-GSD has undergone treatment, the wastewater must meet the standards dictated by state and federal regulations. Historically, sewage discharges from the Connaught Laboratories wastewater treatment plant have contained elevated Biochemical Oxygen Demand (BOD) concentrations. Other aspects of the discharge have been in compliance (see Sections 5.2.1

and 5.2.4). Monthly reports are filed by Connaught Laboratories with the Pennsylvania Department of Environmental Resources (PADER).

2.3.2.3 Solid Waste

Contaminated laboratory materials and animal remains are sterilized by autoclaving prior to incineration in TSI-GSD pathological waste incinerator. No data are available describing the emissions from the TSI-GSD incinerator. However, incineration of organic material at 1,500 degrees Fahrenheit is highly efficient and would produce only small quantities of particulates, carbon dioxide and carbon monoxide (Perkins, 1974). The pathological waste incinerator of TSI-GSD is exempt from permitting by PADER since it was in operation prior to July 1, 1972. This grandfathering remains valid as long as no significant modifications are made to-the incinerator which would alter the characteristics of its emissions. Such changes may be an increase in size or capacity of the incinerator or a change in the type of material being burned. Normal maintenance or replacement of same parts would not affect the permitting exemption (Pennsylvania Public Law 2119 (1959), Air Pollution Control Act) (Disabella, 1992). The incinerator burns at a stack temperature of 1,500 degrees Fahrenheit and is not equipped with scrubbers.

Permit and operation requirements of the Commonwealth of Pennsylvania mandate the microbiological analysis of ash residue from pathological waste incinerators and completion of appropriate forms. The required microbiological analysis consists of one composite sample taken quarterly. These samples are collected and analyzed quarterly by a local environmental contractor. Results are forwarded annually to the Grand Central Sanitary Landfill, located in Northampton County, Pennsylvania, which is permitted by PADER to receive this type of waste (see Appendix C).

2.3.2.4 Infectious Waste

The infectious materials used at TSI-GSD are handled as fluid suspensions (infectious agents in a liquid media). Liquids containing biologically hazardous materials are manipulated using multiple containers so that in the event of breakage, drips, or spills the material is readily controlled and confined. Laboratory wastes which may be potentially infectious (solid and liquid) are autoclaved prior to being removed from the laboratory. Solid waste is subsequently incinerated in TSI-GSD's pathological waste incinerator and liquid wastes are sterilized in one of the three 5,000 liquid waste tanks (see Sections 2.3.2.2 and 2.3.2.3).

2.3.2.5 Hazardous Chemicals

Hazardous chemicals which are used on a regular basis are chloroform, methanol, acetone and formaldehyde. Although not incorporated in the final product, chloroform and methanol are used as intermediates in the production of the Q fever vaccine. Formaldehyde is used as a laboratory sterilant as well as an intermediate in the production of vaccines where it is used for inactivating certain agents. Acetone is utilized as an intermediate in the production of diagnostic reagents.

As a result of interviews with TSI-GSD employees, it was determined that specific SOPs methods for handling of hazardous chemicals at are followed. Chemicals are received in unitized commercial shipping containers. These are monitored upon arrival and then distributed to users within TSI-GSD. Stored chemicals are inventoried and hazard substances survey forms are completed annually. No. 2 fuel oil is the only chemical stored in sufficient quantity to require reporting to state or federal agencies (BCM,, 1990).

Bulk chemicals which are received at TSI-GSD include No. 2 fuel oil, compressed natural gas, liquid nitrogen and carbon dioxide. Chemicals, except No. 2 fuel toil, are stored in a ventilated chemical storage area (Room 10H) or in one of two flammable storage cabinets. The chemical storage room is specifically designed to contain any spills which may occur within it and to vent chemical fumes to prevent their accumulation. It is equipped with fire detection and fire suppression equipment.

Natural gas, carbon dioxide, and liquid nitrogen are piped to locations of use within the building from pressurized tanks located outside the building. Natural gas, carbon dioxide and liquid nitrogen are not classified as hazardous substances but are potential sources of risk to health and property by fire, in the case of natural gas, or decompression, in the case of carbon dioxide and liquid nitrogen. The potential for damage from these substances is at the immediate facility and the threat to the environment from these substances is considered to be minimal since the quantities maintained on-site are small. Areas where natural gas, liquid nitrogen and carbon dioxide are stored are not near work areas. Fire detection equipment is located in key areas of the facility.

Fuel oil is stored underground in a steel tank internally lined with epoxy-coated fiberglass to impede corrosion. The steel tanks are located in an excavated hole which was blasted out of bedrock. This hole was lined with sand and the tanks were buried in the hole. Containment of the fuel in this tank is monitored on a daily basis by TSI-GSD personnel. Each tank is equipped with a gauge measuring tank volume. Tank gauges are certified annually by Approved Tank Cleaning and Lining, Inc. of Allentown, Pennsylvania Potential leakage can be determined by subtracting estimated fuel consumption from tank volume. Pressure testing of the tank is conducted at six month intervals.

Chemical disposal procedures are in accordance with the Resource Conservation and Recovery Act of 1976 (RCRA) (Public Law 94-580; CFR Title 40 Parts 260 and 261). Waste chemicals are collected from usage areas in designated containers and placed in a caged area within the chemical storage room prior to offsite disposal. As is the case for the bulk chemical storage area, the waste chemical area is designed to contain spills. Waste chloroform, methanol and acetone are containerized in holding vessels and are removed by a hazardous waste disposal company to an approved treatment and disposal site. Waste formaldehyde gas is exhausted to the outside after being used to disinfect a laboratory suite. Measurement of the level of formaldehyde gas in outdoor air is estimated to be diluted to concentrations of less than one part per million (ppm) (see Appendix D). There are no permitting requirements for this activity since this procedure was in place before July 1, 1972 and consequently exempted by PADER.

2.3.2.6 Radioactive Materials

There is no history of radioisotope use at TSI-GSD, but future work will require the use of these substances at low levels. Such use, handling, and disposal of radioactive materials at TSI-GSD is under the jurisdiction of the U.S. Nuclear Regulatory Commission (NRC). Radioisotopes will be used to label proteins and nucleic acids for DNA sequencing. TSI-GSD is licensed by the NRC to conduct work with radioisotopes (License Number 3728692-1) (see Appendix E). The license period is from March 6, 1992 through March 31, 1997. TSI-GSD is authorized by the NRC to use hydrogen-3, carbon-14, phosphorus-32, and sulfur-35 in research and development activities (as defined in Section 30.4 of 10 CFR Part 30). TSI-GSD is also authorized to use iodine-125 and iodine-131 in conducting in vitro laboratory studies. Under provisions of this license, radioactive materials may only be used at the TSI-GSD facility, and may not be used in or on human beings, or in activities which would result in release of radioactive material.

Radioactive material must be used by or under the supervision of experienced scientists (specifically named on the license) whose expertise in the use, handling and disposal of radioisotopes has been approved by the NRC. TSI-GSD has a Radiation Safety Officer (RSO) who will be responsible for supervising all work involving radioactive materials. The RSO will assure that TSI-GSD complies with applicable NRC regulations and the terms of the NRC license. The RSO will review all research protocols requiring the use of radioactive materials and will provide expert advise and assistance in the resolution of problems. The RSO will develop and implement use, storage and handling procedures, personnel and laboratory monitoring procedures, maintain accident and incident reports, approve purchase requests, and maintain a record of these activities.

Radioactive materials will be used only in designated areas which have been approved for those uses in the NRC license application process. Radioactive materials must be clearly labeled. The use or storage of food, drinks, cosmetics, or tobacco will not be permitted in any area or room where radioactive materials are present. The safe handling of radioisotopes in the laboratory is detailed in TSI-GSD SOPs.

In accordance with the terms and conditions of its NRC license, TSI-GSD laboratory areas where radioisotopes will be used will be equipped with plexiglass shields for personnel protection, plexiglass blocks for test tubes, and small plexiglass containers for liquids. In addition, all laboratories using radioactive materials must have a plexiglass container for the collection of radioactive waste. The opening of packages containing radioactive material and the distribution of radiolabelled compounds must be performed in the Central Research and

Development Service Area (Room 15, Suite 8) within a fume hood. Isotopes will be dispensed only by authorized users. Currently, there are three authorized users at TSI-GSD Any radioactive material not under the immediate supervision and control of an authorized user will be secured.

Procedures for the disposal of radioactive wastes are detailed in TSI-GSD Saps which incorporate all relevant state, local, and federal regulations and guidelines. Records describing the delivery, use and disposal will be maintained separately for each isotope in accordance with 10 CFR Part 20.401(b) Radioactive material waste disposal procedures vary with isotope, form (solid, liquid), and the type of waste with which it may be mixed (biological, solvent, aqueous). No radioactive waste will be disposed of without the consent and knowledge of the RSO. All radioactive waste material will be labeled with the name of the isotope, its activity, date of assay, and date of disposal.

Solid waste (test tubes, beakers, absorbent paper, gloves etc.) contaminated with radioactive material will be placed in plastic bags and sealed with tape. Hypodermic needles, capillary pipettes and other sharp objects are placed in puncture-proof containers prior to disposal processing. Radioactive material contaminated with infectious material will be sterilized by chemical treatment prior to disposal as radioactive waste. Organic liquid waste (i.e., scintillation vials containing less than 0.05 microcurie hydrogen-3 or carbon-14 per gram of scintillation medium) will be disposed of as chemical waste. TSI-GSD has contracted with Teledeyne Isotopes for the disposal of radioactive waste once such work begins.

Under the terms of its NRC license, TSI-GSD is authorized to hold radioactive material with a physical half-life of less than 65 days (phosphorus-32 and sulfur-35) for decay-in-storage before disposal in ordinary trash, provided that the radioactive waste material is held for a minimum of ten half-lives. A radiologic survey must indicate that its radioactivity is indistinguishable from the level of background radiation before such waste may be disposed of as normal trash. All radiation labels must be removed or obliterated prior to the disposal as normal waste.

Although not included in TSI-GSD's site plan, applicable requirements of 10 CFR Part 20.303 would permit other waste isotope to be disposed of via the sanitary sewer. These wastes include liquid radioactive waste which is readily soluble or dispersible in water, and is diluted in accordance with 10 CFR Part 20, Appendix B. Table II, column 2. Records of the quantities and isotopes of materials disposed of in the sanitary sewer would be maintained by authorized users. Again, although it is allowed, TSI-GSD does not plan to use the sanitary sewer for waste isotope disposal.

2.3.3 Accident Response

2.3.3.1 Hazardous Chemicals

Were a spill to occur, the response would be specific to the nature of the substance involved. The total quantity of hazardous materials on site at the facility is small, but the handling, storage, or use of chemicals means that there is the potential for spills or leaks. TSI-GSD has written procedures for chemical handling and disposal which reduce the probability of accidents. However, the aggregate quantity of all of the hazardous chemical material contained within the facility would not require reporting because the entire inventory is less than any reportable quantity mandated by state and federal regulations.

Spills in the building would be contained and cleaned without involvement beyond the site itself. This is due to physical characteristics of the building (curbing which has been constructed within labs and storage rooms, the presence of impervious laboratory surfaces, and the absence of floor drains). Spill containment is accomplished by curbing designed to contain the total volume of chemicals stored within the room. Chemical spills are handled using a spill cleanup kit consisting of spill pillows and powdered absorption agents.

2.3.3.2 Infectious Agents

The response to spills or accidents involving biological agents is dependent upon the agent, the magnitude and the nature and seriousness of the spill. In the event of a spill, the laboratory worker makes a decision based on SOPs whether to clean up immediately or to evacuate the suite, shower and return for disinfection procedures. Small spills within a biological safety cabinet are absorbed and the surface wiped with an approved disinfectant. Any material used in the cleanup procedure is placed in a biohazard bag and autoclaved.

Spills outside the biological safety cabinet would be considered to be more serious than those within the cabinet. In the event of a spill, the area is immediately flooded with an approved sterilizing agent (bleach, quartenary ammonia compound, or phenolic compound) stored in each laboratory in a 20 liter carboy. Personnel remove their outer clothing at the doorway and leave for a period of time to permit any aerosolized agents to settle. They re-enter the laboratory after 30 minutes in full-coverage Tyvek suits which include shoes and a respirator and apply more disinfectant to the spill area All surfaces in the laboratory are wiped down with disinfectant. Cleanup materials including suits are placed in biohazard bags for autoclaving. After the cleanup procedure, the room is exposed to high-intensity ultraviolet light for one to two hours.

2.3.3.3 Emergency Procedures

In the event that a major accident were to occur at TSI-GSD, an Emergency Coordinator is responsible for conducting all emergency measures. All relevant outside agencies (CDC, PADER, USEPA, Monroe County, Pocono Township) would be notified and provided with detailed information on the nature and extent of any contaminants released beyond the facility buildings. If the Emergency Coordinator deemed that the accident posed a significant environmental and/or human health risk, local officials would be consulted regarding evacuation. Details of the coordination with these outside agencies and specific responsibilities of key personnel are provided in *Preparedness Prevention and Contingency Plan, The Sam Institute-Government Services Division* (BCM, 1990). TSI-GSD has been in operation since 1962 and has no history of accidents of sufficient magnitude to necessitate invoking these emergency procedures. Similar facilities also have never had this type of emergency - the BDRP FPEIS determined that such an emergency is improbable the nature of TSI-GSD is such that no accidents of this nature are envisioned.

In the event of an emergency involving radioisotopes, the roles, responsibilities, and reporting requirements of TSI-GSD workers, RSO, and Radiation Safety Committee (RSC) are defined in SOPs. The RSO and the RSC are responsible for arranging medical care in the event of an emergency situation. Procedures for the handling of emergency situations involving explosion, fire, spills, and medical emergencies are detailed in TSI-GSD SOPs and are consistent with the *Preparedness Prevention and Contingency Plan, The Salk Institute-Government Services Division.*

2.3.4 Accident Investigation

Laboratory accidents are reported directly to the laboratory supervisor. All spills are recorded and a written dog of such events is maintained including suspected cause and exposure. The RSO is responsible for investigating all accidents spills, fires, or other incidents involving radioactive materials. TSI-GSD maintains a Safety Committee composed of two staff members and four hourly employees. Violation of safety regulations including misuse of hazardous materials requires that a written report be prepared and submitted to the Safety Committee. Based on this information, the committee initiates an investigation and prepares a written report of its findings which is submitted to the director. If necessary, disciplinary action is taken.

2.3.5 Orientation and Training

All laboratory work at TSI-GSD is performed under the approximately 250 established SOPs prepared by the staff. These SOPs describe the safe and proper operation of every recurring activity conducted at TSI-GSD and are in compliance with the requirements of Current Good Manufacturing Practices Regulations of the Food and Drug Administration (21 CFR 58). The SOPs incorporate requirements established under federal, state, local and institutional regulations. New employees are required to read and understand the SOPs relative to their duties prior to engaging in these laboratory activities. Periodic review sessions are conducted to ensure that work routines are consistent with SOPs. Review of the adequacy of SOPs is generally performed annually but may be done at shorter intervals when required. Supervised training is also provided to employees when new production schemes are instituted. At approximately annual intervals the Pocono Township Fire Department provides training in fire procedures to TSI-GSD employees.

A general safety manual is distributed throughout TSI-GSD. The SOP on employee health and safety requires that employees with the potential for contact with a pathogenic organism receive appropriate immunization. TSI-GSD is in compliance with federal, state, and local health and safety regulations.

NRC guidelines that individuals working with radioisotopes at TSI-GSD be adequately trained and experienced in the safe use, handling, and disposal of radioactive materials and have received formal training in the principles of radiation and health physics. An education program designed to assure that personnel are fully knowledgeable before they assume duties involving radioactive materials must be completed by TSI-GSD workers involved in radioisotope activities. Training involves securing radioactive materials and restrictions to radioisotope use areas, safety precautions, function and use of protective devices, and reporting of conditions in violation of NRC regulations. A training program for ancillary personnel (i.e., maintenance, engineering and security) and radionuclide users consisting of lectures and video tapes (from the CDC Office of Health and Safety) will be available at TSI-GSD and will detail the properties of radioisotopes, possible radiologic health hazards, and the TSI-GSD Radiation Safety Program. Training for ancillary personnel will be conducted by the RSO or his/her designee in accordance with 10 CFR Part 19. This training will provide a general understanding of radiation, potential health hazards, and the TSI-GSI) Radiation Safety Program.

2.3.6 Safely Inspection and Monitoring

Federal, DoD, and DA regulations require that particular phases of laboratory operations be inspected at periodic intervals. Laboratory equipment is inspected routinely under a preventative maintenance program. Biological safety cabinets and autoclaves are inspected and certified upon installation, annually, and subsequent to relocation within the facility. Inspection of laboratory equipment is performed by the TSI-GSD Quality Assurance Unit.

Care and maintenance of laboratory animals follow guidelines set forth in the Animal Welfare Act. The animal facilities at TSI-GSD are not certified by the American Association for Accreditation of Laboratory Animal Care (AAALAC) but an application is pending (see Section 2.3.7.5).

Routine operations at TSI-GSD adhere to federal, OSHA, and institutional safety regulations. Compliance with appropriate regulations is accomplished through compliance with SOPs. New laboratory personnel receive safety training prior to working with infectious agents. Safety procedures are reviewed when new agents are received and/or when SOPs are revised.

For the last two years, in accordance with USAMRDC policies and regulations, a representative from the Safety Office of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has conducted an annual inspection of the laboratories to ensure adherence to appropriate BL-3 practices. Records of inspections are available from the TSI-GSD Safety Officer and retained on file for at least three years.

Radiation monitoring will be conducted using geiger and scintillation counters. Usage and calibration logs will be maintained for this equipment. All operations requiring the use of radioactive isotopes will follow SOPs which meet or exceed the NRC standards. Safety requirements for working with radioactive materials are described in TSI-GSD SOPs. These safety requirements encompass the use, storage, inventory, and receipt of radioactive material and the personnel protective clothing and equipment required while working with radioactive materials.

Laboratories in which radioactive materials are stored or used must be surveyed at least once per month by wipe testing or survey meter. The RSO is responsible for surveying all such laboratories at least every four months and all laboratories with sealed sources of radiation at least biannually. Radiation monitoring will also be conducted in the event of a spill, leak, fire, or other disturbance within a laboratory, upon cessation of a project requiring use of radioisotopes, before and after modifications to the laboratory, and prior to moving or performing maintenance on laboratory equipment which may contain or may have been used in the vicinity of radioactive materials. Action levels for the initiation of decontamination measures and descriptions of decontamination procedures are detailed in TSI-GSD Radiation Safety SOPs. In addition to standard safety practices applicable for work with any quantity of isotope, work with phosphorus-32 requires real-time monitoring, the wearing of gloves and protective eyewear at all times at the work site, the wearing of film-badges on lab coats, immediate wipe testing of work areas after each use and the wearing of finger extremity monitors if more than one millicurie is used.

2.3.7 Special Considerations

2.3.7.1 Medical Monitoring of Personnel

New employees are given an initial and periodic physical exams before and during their employment at TSI-GSD and receive required immunizations against biological agents used at the facility. Supervisors observe employees on a daily basis for symptoms of infections or unusual behavior. Personnel are monitored at least annually by serosurveillance for infections. Serosurveillance is a measurement of specific antibodies in the bloodstream. Changes in the concentration of these antibodies over time could be an indication that the worker was exposed to an infectious agent. The results of serosurveillance are reviewed and interpreted by the Manager of TSI-GSD. Consultation with a physician is provided to personnel with suspected exposures to infectious agents.

Individuals working with radioactive material are monitored for radiation exposure with film badges. This equipment records the amount of radiation to which the worker has been exposed. The badges will be exchanged by Keystone Medical X-Ray, Inc. every three months. Work areas will be monitored for radiation using wipe tests and geiger counters when activities involving radioisotopes are being conducted. The quantities of radioisotopes used are extremely small and therefore do not require urine testing or other bioassays of personnel (10 CFR Part 20, Standards for Protection Against Radiation).

2.3.7.2 Use of Recombinant DNA

There is no history of experimental recombinant DNA use at TSI-GSD but GEMs will likely be used in the future. However, TSI-GSD has produced vaccines from recombinant organisms, and in each case the recombinant technology and the organisms used were developed elsewhere. For example, TSI-GSD is currently producing pilot lots of an anthrax vaccine prepared from a small portion (called the protective antigen, or PA) of the entire anthrax organism. The genetic material coding for the production of the PA has been inserted into a baculovirus, a virus that infects moth cells *(Spodoptera frugiperda)*, but does not infect man. This inserted genetic material is translated during the replication of the baculovirus in the moth cells, releasing PA into the growth medium. The genetic material that codes for anthrax toxin and other parts of the anthrax bacterium is not in use nor is it available at TSI-GSD. Thus the use of baculovirus to express (produce) PA is absolutely harmless to workers and to the community.

All recombinant DNA work will be conducted in accordance with the Guidelines for Research Involving Recombinant DNA Molecules (Federal Register, May 7, 1986). The research methods and safety/containment practices utilized in the work with *High Hazard Organisms* are equivalent to the safety guidelines recommended for work with recombinant DNA. All individuals working with recombinant DNA will be trained in the safe conduct of vaccine production and work with *High Hazard Organisms.* The baculovirus-PA is not toxic or infectious to humans. TSI-GSD IBC, composed of scientists with expertise in recombinant DNA as well as members of the local community, will oversee all activities involving recombinant DNA. The currently planned TSI-GSD work involving recombinant DNA will not significantly alter the qualitative or quantitative characteristics of the TSI-GSD waste stream. SOPs implementing these requirements of the Guidelines are in place and will be in effect prior to initiation of work.

2.3.7.3 Aerosol Testing

Aerosol testing using infectious biological agents has never been performed at TSI-GSD. Moreover, there are no capabilities within the facility to produce aerosols and there is no requirement for such work to be performed at TSI-GSD.

2.3.7.4 Shipment of Etiologic Agents

Etiologic agents are occasionally shipped to and from TSI-GSD. Appropriate packaging and labeling requirements (42 CFR Part 72; 49 CFR Part 173.387) are followed when transport of these biological agents is necessary. The method of shipment used routinely is courier-accompanied ground transportation.

2.3.7.5 Laboratory Animal Care and Use

TSI-GSD almost exclusively uses rodent species in its operations but occasionally uses non-human primate species. Animals are used only for vaccine safety and potency testing. Animal handling practices and the quality of care at TSI-GSD are in accordance with the *Guide for the Care and Use of Laboratory Animals, HHS* Publication No. 86-23, 1985. All laws and regulations pertinent to laboratory animal care and use are complied with by TSI GSD. Care and maintenance of laboratory animals follow guidelines set forth in the Animal

Welfare Act (9 CFR). Unannounced inspections are conducted at least annually by the U.S. Department of Agriculture (USDA). The animal facilities are not certified by AAALAC, but an application for certification is pending.

Personnel are protected from exposure to infectious agents when using animals by adhering to the requirements of the appropriate Animal Biosafety Level (ABL). ABLs include animal handling practices, protocols, equipment and facilities appropriate for work with infected animals and correspond to level of risk associated with Biosafety Levels (CDC, 1988). ABL-3 animal practices are used for animals when required. These practices include decontamination of all surfaces after spills, prohibition of smoking, eating, and drinking in animal rooms, washing of personnel hands after handling cultures, and inward opening doors to rooms housing infected animals.

In addition to these procedures, cages are autoclaved prior to cleaning activities, and personnel must wear protective boots, surgical masks, gloves and solid-front/wrap-around type gowns when work with infected animals is in progress. All animal wastes are autoclaved and incinerated. Leak proof containers are used when transporting animal carcasses. Laboratory managers/supervisor advise personnel of potential hazards and access to rooms housing infected animals is restricted to only necessary individuals. HEPA filtration is required and is incorporated into the exhaust of the laboratory ventilation system of TSI GSD. Any necessary measures to prevent or reduce generation of incidental aerosols during laboratory activities at TSI-GSD are implemented. A clean hall/dirty hall layout is used to further reduce the risk of contamination. In this arrangement, new materials enter the laboratory from only one direction and used materials are removed by the opposite direction. Consequently, new materials are never co-mingled with potentially contaminated substances.

Animal rooms are physically separated from main corridors of TSI-GSD. Access doors are self-closing. Newly arrived laboratory animals are quarantined to ensure good health.

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3.0 ALTERNATIVES CONSIDERED

3.1 Programmatic Alternatives - BDRP EPEIS

Particular alternatives to the conduct of biomedical RDT&E by the Army have been addressed previously in the BDRP FPEIS. These options included discontinuance of activities with high-hazard organisms and GEMs. These alternatives were examined in detail in sections 4.2.1, 4.2.2 and 4.3 of the BDRP FPEIS and are included here as Appendix F. That analysis concluded these alternatives would not substantially mitigate any negative environmental impacts or consumption of resources. Consequently, these options will not be evaluated further in this EA because they are not considered reasonable alternatives and because they are programmatic issues. This assessment considers specific alternatives focused on the continued operation of TSI-GSD. Environmental impacts of the proposed action and the alternatives identified below are considered in Section 5.0.

3.2 Alternative I - Transfer the USAMRDC Sponsored Work at TSI-GSD to Another Location

This alternative entails continuing the work conducted at TSI-GSD at a different geographical location. This alternative would cause suspension of that part of BURP and IDRP efforts performed at TSI-GSD, and transfer of these operations to other facilities.

3.3 Alternative II - No Action Alternative

The no action alternative is to cease the work presently supported under the USAMRDC contract with TSI-GSD.

3.4 Alternative III - Continue the Operation of TSI-GSD in its Present Scope

This alternative involves continued production of biological products at this location in its present scope. This alternative is considered to be the preferred option since these efforts are considered essential to the BDRP and IDRP missions and are authorized by Congress.

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4.0 AFFECTED ENVIRONMENT

4.1 Environmental Setting

The general setting of the TSI-GSD is rural. Connaught Laboratories and TSI-GSD are the only facilities within a half mile classified as industrial by municipal zoning regulations. The Pocono Mountain Junior Senior High School is located approximately one-half mile north of the TSI-GSD/Connaught Laboratory complex The majority of development along Route 611, where TSI-GSD is located, is strip-development, consisting of restaurants, motels, and retail establishments. Other than Connaught Laboratories, the nearest commercial neighbor of TSI-GSD is the Swiftwater Inn which is located approximately 350 feet from the TSI-GSD property.

All production and administrative activities of TSI-GSD are located within the facility complex Support functions such as-final wastewater treatment are provided by the adjacent Connaught Laboratories. Environmental characteristics of the area around TSI-GSD are presented in the subsequent sections. Most of these environmental components are determined to have little probability of being negatively impacted by operations at TSI-GSD. Material describing the evaluation of the affected BDRP environment in a programmatic context are presented in Appendix G.

4.1.1 Land Use

The existing land use pattern at TSI-GSD conforms to the current and future plans for development within Monroe County. L and use within the vicinity of TSI-GSD is regulated by Monroe County, Pennsylvania. Municipal jurisdiction is exercised by Pocono Township. These local governments maintain Comprehensive Plans, establish zoning ordinances, and regulate development on lands within their jurisdiction, including land within the installation boundaries. The region surrounding TSI-GSD is comprised of agricultural, commercial and residential areas.

Development along Route 611 is principally commercial development in a strip fronting the road, predominantly retail shopping and lodging. TSI-GSD and Connaught Laboratories properties are zoned for industrial use by Pocono Township (Pocono Township Ordinance Number 16, Pocono Township Ordinance Number 34). This land use designation permits the manufacture of biological pharmaceutical products. TSI-GSD holds an Occupancy Permit from Pocono Township (see Appendix H) and must obtain a Building and Zoning Permit when additional construction is undertaken. TSI-GSD has no history of permit denial from Pocono Township.

4.1.2 Plant and Animal Ecology

The distribution and abundance of wildlife within a geographical area are dependent upon soil type and quality, availability of vegetation and shelter as well as human land use patterns. Approximately 77 percent of Monroe County is covered by forests (Soil

Conservation Service (1991). Dominant trees include oak, hickory, gum, elm, ash and red maple. The area is inhabited with numerous wildlife species including white-tailed deer, black bear, snowshoe hare, gray squirrel, cottontail rabbit, ruffed grouse, bobwhite quail, ringed-neck pheasant, woodcock and several species of waterfowl. A list of wildlife species potentially found in Monroe County is provided in Appendix I.

Examples of the three basic habitat types (open land, woodland, wetland) found in Monroe County are located within one half mile of TSI-GSD. There are no known site specific studies describing the plant and animal communities within the property of TSI-GSD. Openland provides habitat for pheasant, meadowlark, field sparrow, cottontail rabbit and red fox, which utilize the grain and seed crops, grasses, and legumes produced by the cropland, meadows and areas overgrown with grasses and small shrubs. This type of habitat is characterized by the presence of meadows and overgrown farmland.

The woodland areas of Monroe County provide habitat for wild turkey; ruffed grouse, woodcock, thrushes, woodpeckers, squirrels, gray fox, raccoon, deer and bear. These areas are populated with hardwoods and conifers, grasses, legumes and other wild herbaceous plants.

The Monroe County wetlands habitats provide food and shelter for ducks, geese, herons, shore birds, muskrat, mink and beaver. These open, shallow water areas may be marsh or swamplike and contain numerous species of annual and perennial herbaceous plants. U.S. Fish and Wildlife Service (USFWS) National Wetlands inventory maps indicate numerous wetland habitats are present within several miles of the facility. The edge of the nearest wetland is approximately 1,000 feet from the facility.

Two endangered species, the bald eagle *(Haliaeetus cephalus)* and the peregrine falcon *(Falco peregrinus)* may utilize the habitat found in Monroe County. Both are listed on the USFWS list of Threatened and Endangered Plant and Animal Species. Bald eagles and peregrine falcons would utilize this area during migration. Bald eagles are associated with timberland near streams, while peregrine falcons would utilize more open areas such as cropland and grassland. Despite the suitability of habitat, neither species is known to frequent the area near Swiftwater (see Appendix I).

A number of Pennsylvania-listed endangered, threatened, or species of special concern may also utilize the habitat found in Monroe County (Appendix I). These are organisms which may be rare within the Commonwealth of Pennsylvania but are not considered to be special status species on a national basis. None of the Pennsylvania-listed endangered, threatened, or species of special concern are known to frequent the area near TSI-GSD.

4.13 Geology

Monroe County is situated in an area of glacial geology in the mountainous area of eastern Pennsylvania. Elevations in Monroe County range from 404 feet along the Delaware

River to over 2,200 feet at Pimple Hill. The northern two-thirds of Monroe County is located in the Pocono Plateau section and Glaciated Low Plateau section of the Appalachian Plateaus province. The southern third of Monroe County is in the Appalachian Mountain section of the Valley and Ridge province (Soil Conservation Service, 1981)

Devonian rocks underlay the northern area of the county. These rocks are primarily Catskill Formation, but also include marine beds, Hamilton Group and Onondaga Formation. The southern tenth is underlain by Silurian rocks. The structural geology of the Pocono Plateau section of the county has bedrock which dips southeastward. The Appalachian Mountain section of the county is more complex with both anticlinal and synclinal features. Glacial deposits include stratified and unstratified drift and lacustrine deposits each having its own distinct topographic and lithologic features. Geologically, TSI-GSD is situated in a transitional area immediately south of the Pocono Plateau. This latter area is elevated relative to Swiftwater Creek and is a major groundwater recharge area in Monroe County. Consequently,- groundwater in the immediate vicinity of the Pocono Plateau tends to flow in a southeasterly direction towards TSI-GSD.

TSI-GSD building is on the eastern portion of the property and is underlain by the Oquaga-Lackawanna soil type. This soil is considered to be extremely silty loam and is found in 8 to 25 percent slopes. Both permeability and available water capacity are low to moderate. These soils are most often utilized for woodland since their stony character makes them poorly suited for cultivating crops and pastureland. In addition, partially-weathered bedrock sandstone may be encountered at approximately 26 inches below the soil surface. The western portion of TSI-GSD property consists of a parking lot and is underlain by Chenango gravelly loam with three to eight percent slopes. In contrast to the Oquaga-Lackawanna soil type, this soil is characteristically well drained, contains less cobbles, and has moderate potential for crops, pasture and woodland (Soil Conservation Service, 1981).

4.1.4 Water

Water for TSI-GSD is obtained from an on-site well originating approximately 400 feet below the ground surface. The well has been in service since at least 1974 and has a capacity of 216,000 gallons per day. The average water use by TSI-GSD is approximately 20,000 gallons per day (574,000 gallons per month).

The chemical quality of the groundwater from this well is similar to other wells in the region. Between 1987 and 1990, monthly monitoring of the well water indicated that detectable concentrations of trichloroethylene (TCE) were present (Table 4-1). The highest concentration recorded is 9.7 micrograms per liter. The USEPA recommends that the Maximum Contaminant Level (MCL) for TCE in drinking water is 5 micrograms per liter. However, the concentrations of TCE have been decreasing since 1989 and it has not been detected since September of that year. TCE levels have been in compliance for the past 12 consecutive quarters and have been undetectable for the past six consecutive quarters. The source of the contamination is likely a USEPA Superfund hazardous waste site (Kalins)

Table 4-1. Concentrations of Trichloroethylene (TCE) in TSI-GSD Well Water (Data compiled from the files of the PADER)

Month/Year	Concentration (micrograms/liter)	Month/Year	Concentration (micrograms/liter)
6/87	<2.0	7/89	1.8
7/87	<0.5	8/89	2.3
8/87	1.00	9/89	0.7
9/87	1.79	10/89	<0.5
10/87	<0.5	11/89	<0.5
11/87	0.62	1/90	<0.5
12/87	<0.5	2/90	<0.5
1/88	9.7	3/90	<0.5
2/88	6.4	4/90	<0.5
3/88	<0.5	5/90	<0.5
4/88	-	6/90	<0.5
5/88	1.6	7/90	<0.5
6/88	4.5	8/90	<0.5
7/88	4.2	9/90	<0.5
8/88	3.0	10/90	<0.5
9/88	2.4	11/90	<0.5
10/88	3.5	12/90	<0.5
11/88	3.0	1/91	<0.5
12/88	2.6	2/91	<0.5
1/89	5.7	5/91	<0.5
2/89	2.8	8/91	<0.5
3/89	5.5	10/91	<0.5
4/89	1.96	2/92	<0.5
5/89	4.4	5/92	<0.5
6/89	6.0		

which is located approximately three miles northwest of TSI-GSD. This site is hydrologically upgradient from TSI-GSD and TCE has also been detected in a spring situated between the hazardous waste site and TSI-GSD. At the present time, the source of the TCE in TSI-GSD well water has not been definitively determined. It is possible the contamination is indicative of general water quality conditions of northeastern Pennsylvania groundwater. TCE has never been used at TSI-GSD.

Well water is not used for drinking purposes at TSI-GSD because of the earlier problem with TCE. Instead, commercially bottled water is provided to the employees for consumption. The original plumbing at TSI-GSD did not guarantee a twenty minute contact with chlorine; therefore, a UV water treatment system was installed recently. The water distribution system of TSI-GSD is classified by the state as a non-transient, non-community public water system since it serves more than 25 of the same people more than 60 days of the year. A detailed inspection of the water distribution system has been completed by the PADER. This inspection consisted of an examination of the well, well construction, and water distribution system and concluded that the water distribution was in compliance with relevant standards of the Commonwealth of Pennsylvania. Quarterly water quality tests have consistently been in compliance.

Wastewater originating from the laboratories is held in 5,000 gallon, glass-lined tanks and sterilized prior to discharge to the sewage treatment plant owned by Connaught Laboratories. Non-laboratory wastewater also is processed at the treatment plant however, it does not pass through the TSI-GSD sterilization tanks. Wastewater from both biomedical operations are subjected to secondary sewage treatment. The final effluent is discharged into Swiftwater Creek. The creek flows into Swiftwater Lake which is a man-made impoundment located approximately two and one-half miles downstream from the Connaught Laboratories wastewater treatment plant. Swiftwater Creek eventually empties into the Delaware River.

Connaught Laboratories, which contracts with the U.S. government and the private sector, holds a NPDES permit allowing the discharge to enter the stream if certain criteria are met, and is responsible for compliance with all discharge standards. A private contractor collects effluent samples monthly and analyzes them for 12 parameters including bacteriological, chemical and physical characteristics. The monitoring is consistent with requirements prescribed by EPA and the PADER. The Commonwealth of Pennsylvania classifies Swiftwater Creek as *High Quality - Cold Water Fishery (HQ-CWF)* with suitable habitats and conditions for coldwater fish. State officials believe the creek is inhabited by two recreationally-important fish species - brook trout and brown trout, but lack population data. The *HQ-CWF* designation mandates special protection defined as *maintenance of excellent quality waters and environmental or other features that require special water quality protection.* Consequently, pollutant discharges to these types of water bodies are stringently limited.

4.1.5 Air Quality

The air quality at TSI-GSD, as well as in Monroe County, is good. A lack of large industrial point sources within the region is the principal reason for the current air quality. The air quality of Monroe County is regulated by PADER Bureau of Air Quality Control. Monroe County is located in Region II North The National Ambient Air Quality Standards are incorporated into the standards set by the state agency. The Commonwealth of Pennsylvania incorporates the Code of Federal Regulations (CFR) for air quality standards implemented pursuant to the Clean Air Act. Citations include 40 CFR Parts 50, 51, 52, 57, 60, 61, 80, and 82. Subjects covered include ambient standards, new stationary sources, hazardous pollutants and related topics.

4.1.6 Agriculture

According to the 1982 Census of Agriculture, Monroe County has 207 farms totaling over 29,000 acres of land. Of the 207 farms, only two have irrigation, with the principal source of water being wells on the farm. The nearest farm is located more than two miles from the TSI-GSD.

4.1.7 Cultural Resources

4.1.7.1 Historical

There are no known facilities in Monroe County which are entered on the National Register of Historic Places. There are, however, significant historical structures eligible to be listed on the Register near the site (see Section 4.1.7.2).

4.1.7.2 Archaeological

An archaeological survey has not been performed at TSI-GSD. No sites of archaeological importance have been uncovered at TSI-GSD in the course of past construction and maintenance activities. There is a high probability that archaeological resources are located near the Swiftwater Inn according to the Pennsylvania Bureau for Historical Preservation (Carr, 1992). The Swiftwater Inn is located approximately 100 yards from TSI-GSD property.

4.1.8 Climate

The parts of the county at lower elevations have slightly warmer temperatures (four degrees) and slightly less precipitation (about four inches) than those at higher elevations. Annual precipitation in Monroe County averages 44 to 45 inches. Rainfall peaks during June, July and August and the average relative humidity is 50 percent. Prevailing winds are from the northwest and average seven miles per hour.

4.1.9 Energy Resources

Depletable resources consumed by TSI-GSD include natural gas and fuel oil.

4.1.10 Sociological

Monroe County had a reported 1990 population of 103,169 and a 1980 population of 69,409. Proportions of the population by race in 1980 were approximately 98 percent White, 1.4 percent Black and 0.6 percent Other. The 1989 population was estimated at 93,127 - an increase of approximately 34 percent since 1980. The number of households reported in 1980 was 25,170 and the number estimated for 1989 was 35,493 - an estimated increase of approximately 41 percent. Greater than *55* percent of the households in Monroe County have either one or two occupants.

4.1.11 Noise

At TSI-GSD, noise is treated primarily from an industrial health perspective. There are no known quantitative studies of the ambient noise environment at TSI-GSD or off-site. The PADER and Pocono Township have no records of complaints of excessive noise against TSI-GSD.

4.1.12 Odors

Production of vaccines at TSI-GSD requires that considerable waste material be rendered sterile through heat treatment and incineration. This material includes contaminated laboratory materials, animal remains and wastewater. While steam heating and incineration provide effective treatment and disposal of infectious waste, there may be associated odors that are transiently offensive. These odors are localized in area and time, and are rapidly dispersed in the ambient atmosphere. There are no records of complaints of offensive odors from the TSI-GSD.

4.1.13 Economic Environment

4.1.13.1 Employment

According to the Pennsylvania Department of Labor and Industry, the number of employed persons in Monroe County during May 1992 was slightly greater than 45,200. The unemployment rate was approximately 103 percent for the same period.

4.1.13.2 Income

According to the U.S. Census Bureau, the aggregate household income for 1990 was $692,254,000. The median household income was approximately $32,500. More than 1,100 households had income below the poverty level. In about 30 percent of those households with income below the poverty level, the householder was at least 65 years old.

4.1.13.3 Property Values

In 1980 there were 37,222 housing units in Monroe County. The aggregate value of owner-occupied or vacant-for-sale non-condominium units was $735,404,000 with a median value of approximately $47,200. The U.S. Census Bureau estimated the number of housing units available in Monroe County increased to 54,823 by 1990. The median value of owner-occupied or vacant-for-sale non-condominium units in 1990 was $116,500.

4.1.14 Public Opinion

Potential issues of public concern at the local level relate to the daily operation of TSI-GSD. These issues include generation of offensive odors, waste stream management and waste stream disposal. Pocono Township has no records of negative local public opinion regarding these issues.

4.1.15 Transportation

4.1.15.1 Road

Swiftwater is accessible by two major interstate highways, Interstate 80 and Interstate 380. The town of Swiftwater is located on U.S. Route 611.

4.1.15.2 Rail

No passenger rail service is available in the immediate vicinity of Swiftwater or TSI-GSD. Passenger train service runs through Philadelphia and Harrisburg.

4.1.15.3 Air

Commercial airline service is available to the Swiftwater area through the airports located in the Scranton, Allentown and Philadelphia metropolitan areas. Swiftwater is approximately 45 miles from Wilkes-Barre Scranton International Airport, approximately 60 miles from Allentown-Bethlehem-Easton Airport, and approximately 130 miles from Philadelphia International Airport.

4.1.15.4 Traffic

The transportation needs of TSI-GSD are served adequately by the existing highway system.

4.1.16 Communication

Communication outside of TSI-GSD is accomplished by commercial telephone or fax machine. Two internal communication systems exist: a public address/paging system and an intercom system.

5.0 ENVIRONMENTAL AND SOCIOECONOMIC CONSEQUENCES

5.1 Introduction

An evaluation of the current and potential environmental consequences of operations at TSI-GSD is presented in this section. The proposed action and alternatives considered are analyzed relative to the conduct of currently planned and routine activities. As detailed below, this analysis concludes that no significant adverse environmental effects are associated with continuation of present activities at TSI-GSD. Moreover, positive benefits to the economy of Monroe County and to the defense posture of the U.S. were identified. These conclusions are based upon an evaluation of current activities at TSI-GSD and any associated environmental impacts, potential adverse impacts resulting from cumulative effects, and an analysis of the potential for release of high-hazard microorganisms to the surrounding environment. The proposed action was evaluated after comparisons with the alternatives considered. It was concluded that continuation of production and testing activities at TSI-GSD has more positive attributes than the proposed alternatives.

The potential environmental effects associated with the various BDRP risk/issue categories were discussed in the BDRP FPEIS. Controversial programmatic issues and program administration are not discussed in this EA. Appendices J and K, respectively, contain relevant material describing programmatic risk/issue category characteristics and environmental and socioeconomic areas of potential concern. Significant relevant areas of concern identified for each programmatic risk/issue category by Impact Analysis Matrix (IAM) evaluation are presented in Appendix L.

5.2 Environmental Consequences of Routine Operations

The IAM analysis of TSI-GSD presented in the BDRP FPEIS (Figure 5-1) was used to identify and carefully scrutinize areas of potential concern which were examined further to determine the nature of the impacts arising from operations of TSI-GSD. Each major component is discussed here regardless of the presence or absence of actual impacts. It is in the context of the baseline environment of TSI-GSD, described in Chapter 4 of this EA, that these analyses were made. Section 5.2 identifies the potential impacts of TSI-GSD operations on each identified area of potential concern. Each identified area is examined in further detail to determine the magnitude and significance of actual impacts.

5.2.1 Surface Water and Groundwater

There are no significant environmental effects on surface water related to routine operations of TSI-GSD. TSI-GSD wastewater is discharged to the Connaught Laboratories wastewater treatment plant where it receives secondary sewage treatment. The effluent then is discharged to Swiftwater Creek. The Connaught Laboratories wastewater treatment plant

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LEGEND
H - HIGH
L - LOW
+ - POSITIVE

	POTENTIAL AREAS IMPACTED	ACTIVITIES: RESEARCH DEVELOPMENT TESTING AND EVALUATION: LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	ADMINISTRATION AND MANAGEMENT: OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	RELEVANT AREAS OF CONCERN: S	M
CONTROLS	OPERATIONAL	✓	✓	✓	✓	✓		✓	✓	✓					
	SAFETY	✓	✓	✓	✓	✓		✓	✓						
	SECURITY	✓	✓	✓	✓	✓		✓	✓						
	REGULATORY		✓	✓	✓	✓		✓	✓	✓	✓				
	PERCEIVED	L	-	H	L	-	-	-	L	-	-				
	ACTUAL	L	L	L	L	L	·	L	L	-	-				
BIOPHYSICAL	1. LAND USE: Agriculture														
	Industrial														
	Commercial														
	Residential														
	Reacreation														
	Wetlands														
	Floodplains														
	Unique Geographical Area														
	Policies														
	2. PLANT AND ANIMAL ECOLOGY: Population														
	Terrestrial Habitats														
	Aquatic Habitats														
	Endangered Species														
	3. GEOLOGY: Soils														
	Topography														
	Erosion														
	4. WATER: Surface			L				L	L			L	L		✓
	Ground														
	5. AIR QUALITY: Ambient Standards			L				L	L			L	L		✓
	Biological			L				L	L			L	L		✓
	6. AGRICULTURE: Crops														
	Livestock														
	7. CULTURAL RESOURCES: Historical														
	Archeological														
	8. ENERGY RESOURCES: Depletable Supplies							L	L						
	Non-Depletable														
SOCIOECONOMIC	9. SOCIOLOGICAL ENVIRONMENT: Demographics														
	Aesthetics														
	Noise														
	Odor							L							
	10. ECONOMIC ENVIRONMENT: Labor Force	L+		L+		L+		L+		L+	L+				+✓
	Economic Activity							L+							
	Property Values														
	11. PUBLIC OPINION: Controversial Issues				L										
	Social Concerns														
	12. PROGRAM BENEFITS: National Defense Posture	L+	L+	H+		L+		H+			L+	H+	L	+✓	
	Scientific Benefit	L+	L+	L+		L+					L+	L	L		+✓
	Public Benefit		L+	L+		L+									+✓
	13. TRANSPORTATION: Road														
	Rail														
	Air														
	Traffic							L							
	14 HUMAN HEALTH: Workforce	L	L	L	L	L						L	L		✓
	General Population											-	L		
	15. SAFETY: Construction							L							
	Occupational	L	L	L	L	L		L	L			L	-		
	Accidents	L		L	L	L		L				L	-		
	SIGNIFICANT	-	-	-	-	-		-	-	-	-				
	MINOR	-	+✓	✓	✓	✓		+✓	-	-	✓				

Figure 5-1 Summary Impact Analysis Matrix for TSI-GSD

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processes wastes from both Connaught and TSI-GSD. Approximately 20,0(10 gallons of wastewater per day are generated by TSI-GSD. The volume of wastewater from TSI-GSD is mostly general wastewater (90 percent) with the remainder (10 percent) coming from laboratory waste. The average wastewater contribution by TSI-GSD to the Connaught treatment facility constitutes 16 to 18 percent of the total wastewater volume handled at the plant (Kirby, 1992a).

Swiftwater Creek is classified as HQ-CWF by the Commonwealth of Pennsylvania (Pennsylvania Code; Title 25, Part I, Subpart C, Article II, Chapter 93) and consequently the amount of pollution it can receive is strictly limited. In general, the discharge to Swiftwater Creek from the Connaught Laboratories wastewater treatment plant has been in compliance with current NPDES standards with the exception of BOD concentrations, Total Suspended Solids (TSS) and pH (Appendix M). The BOD concentration averaged 10 percent more than the amount permitted by the PADER for this wastewater treatment facility for the period May 1990 through November 1991. Because the production activities conducted by TSI-GSD and Connaught Laboratories are very similar, the contribution of TSI-GSD to elevated BOD concentrations is proportional to the volume of wastewater TSI-GSD delivers to the plant (i.e., 16 to 18 percent) (Kirby, 1992a). In a hypothetical sense, potential negative impacts to the creek would be associated with grossly elevated levels of nitrogen, phosphorus, fecal coliform bacteria, BOD, suspended solids, and depressed dissolved oxygen concentrations in the effluent. Elevated concentrations of these parameters directly or indirectly cause dissolved oxygen levels in the creek to decrease. Significant reduction in dissolved oxygen concentrations would result in death of sensitive aquatic organisms, particularly coldwater fish, which are the most susceptible to organic pollution (Wetzel, 1975). Fish kills or die-offs of aquatic organisms related to routine operations of Connaught Laboratories wastewater treatment plant have not been observed in Swiftwater Creek. Data collected by the Monroe County Planning Commission in 1988 (Monroe County Planning Commission and Pennsylvania Department of Environmental Resources, 1988), 1990 (Monroe County Planning Commission and Pennsylvania Department of Environmental Resources, 1990), and 1991 (Monroe County Planning Commission and Pennsylvania Department of Environmental Resources, 1991) from locations approximately one half mile upstream and downstream from the effluent outfall (including measurements of BOD, TSS and pH) do not indicate significant impacts to Swiftwater Creek (Table 5-1). The data provided in Table 5-1 are consistent with water quality standards for this class of water body in the Commonwealth of Pennsylvania for protection of aquatic life (Pennsylvania Code; Title 25, Part I, Subpart C, Article II, Chapter 93).

The Connaught Laboratories wastewater treatment plant is permitted by the Commonwealth of Pennsylvania to discharge the effluent into Swiftwater Creek (Industrial Permit No. PA-0060071). This permit will expire on March 20, 1996. The Connaught Laboratories wastewater treatment plant has recently been modified and upgraded to reduce BOD and TSS concentrations in the effluent. Modifications completed in October 1991 increased the capacity of the plant to 175,000 gallons per day. The plant is permitted to process 150,000 gallons per day but operates at an average volume of 90,000 gallons per day. The recent improvements to the Connaught Laboratories provided ozonation (the addition

Table 5-1. Comparison of the Chemical Characteristics[1] of Swiftwater Creek Upstream and Downstream from the Connaught Laboratories Treatment Outfall (Data compiled from the files of the Monroe County Planning Commission)

Chemical Characteristic	Upstream			Downstream		
	1988	1990	1991	1988	1990	1991
Dissolved Oxygen	8.0	13.4	8.7	7.4	12.6	9.5
pH	6.96	7.26	7.22	7.09	7.34	7.14
Specific Conductance	80	79.8	83.8	100	95.5	103.9
Total Hardness[2]	19.6	18.0	18.0	33.3	21.00	22.2
Total Alkalinity[2]	10.0	11.0	10.4	18.0	13.5	12.6
Nitrogen-Nitrite	<0.005	0.272	ND[3]	<0.005	0.361	ND
Nitrogen-Nitrate	0.154	<0.002	0.337	0.176	0.002	0.577
Nitrogen-Ammonia	<0.05	<0.05	ND	<0.05	<0.05	ND
Total Phosphorus	0.021	<0.03	ND	<0.03	<0.03	0.054
Fecal Coliform Bacteria[4]	<10	<20	<20	<10	40	<20
BOD	3.99	<1.0	ND	<0.5	<1.0	ND
Total Suspended Solids	<2.00	1.14	1.00	<2.00	1.71	1.00

[1] All units are milligrams/liter except for pH (pH units) and specific conductance (micromhos/centimeter).
[2] Milligrams/liter as calcium carbonate
[3] No Data
[4] Numbers per 100 milliliters

of triatomic oxygen) to the final effluent. Ozonation oxidizes (decomposes) organic matter (Gaudy and Gaudy, 1980), and thus reduces the BOD concentration in the effluent discharged into Swiftwater Creek. The Connaught Laboratories wastewater treatment plant has been in compliance with the NPDES requirements for BOD since May 1991 (Appendix M). Between December 1991 and May 1992, the BOD concentration of the effluent has been more than 70 per cent below the amount allowed by the NPDES standard for the Connaught Laboratories wastewater treatment plant. The recent non-compliance in requirements for pH is related to adjustments to the operations of the upgraded wastewater treatment plant.

Under current permitting requirements, the effluent does not need to comply with any standards for heavy metals but monitoring of metal concentrations is required. However, the effluent will be subjected to restrictions for lead, mercury and copper after March 26, 1994. These new standards do not allow metal concentrations greater than 37 parts per billion (ppb) copper, 10 ppb lead and 0.2 ppb mercury. Under current conditions the effluent from the Connaught Laboratories wastewater treatment plant does not meet these standards. The high concentrations of copper and lead in the effluent from the Connaught Laboratories wastewater treatment plant are due to the chemical nature of the groundwater utilized by the two facilities. The groundwater used by TSI-GSD and Connaught Laboratories is aggressive (corrosive) towards lead and copper pipes and fittings. The corrosive nature of the groundwater causes water flowing through pipes to chemically strip lead and copper from the plumbing and results in higher concentrations of lead and copper in the effluent than was originally in the groundwater. The high concentrations of mercury in the effluent are unrelated to groundwater characteristics. Sources within Connaught Laboratories and TSI-GSD contribute mercury to the effluent. TSI-GSD and Connaught Laboratories are currently attempting to determine the source of mercury and evaluating recovery methods from their wastewaters prior to discharge to the wastewater treatment plant. A joint committee composed of representatives from Connaught Laboratories and TSI-GSD is also evaluating methods of attaining compliance with standards for copper and lead. Currently, injection of polyphosphates into the water prior to use within each facility is being evaluated as a means of mitigating the corrosive characteristics of the water, thereby reducing the metals stripped from the piping (Kirby, 1992a).

For the period May 1990 to May 1992 the effluent from the wastewater treatment plant averaged concentrations of 118 ppb copper, 12 ppb lead, and 2.5 ppb mercury (Appendix M). These concentrations represent approximately three (copper), two (lead) and 13 (mercury) times the amount which will be allowed after March 26, 1994. The USEPA has derived Ambient Water Quality Criteria for a number of contaminants including copper (USEPA, 1985a), lead (USEPA, 1985b) and mercury (USEPA, 1985c). These values are based on the toxicity of these contaminants to a wide variety of aquatic life. These criteria are designed to be protective of greater than 95 percent of aquatic species (USEPA, 1985a; USEPA, 1985b; USEPA, 1985c). The specific criteria represents the maximum in- stream concentration of the contaminant. The Ambient Water Quality Criteria for acute toxicity of copper, lead, and mercury are, respectively, 18 ppm (18,000 ppb), 83 ppm (83,000 ppb) and 2.4 ppm (2,400 ppb). These concentrations represent in-stream concentrations and are not directly comparable to the concentrations of these metals in the effluent since the discharge from the wastewater treatment plant will be immediately diluted when mixed with water from Swiftwater Creek. The average concentrations of copper, lead, and mercury are well below the acute toxicity values prior to dilution in the creek. Dilution rates are dependent upon flow rates, which vary seasonally. Detailed flow data are not available for the Swiftwater Creek in the region around the Connaught Laboratories and TSI-GSD facilities (Kolva, 1992). Limited flow data (obtained two to three times per year) are available for 1985 and annually for 1988 through 1991 (Surma, 1992). However, approximations can be made using measured flow rates within the watershed of Swiftwater Creek. Estimated flow rates are taken in account in determining the metal standards for the NPDES permit.

Maintenance of the *HQ-CWF* designation attached to the water body by the Commonwealth of Pennsylvania combined with historical compliance with stringent NPDES permit restrictions indicates the environmental effect of the effluent discharge from the Connaught Laboratories wastewater treatment plant are minor. Moreover, continued upgrades to the Connaught Laboratories wastewater treatment plant will further reduce concentrations of BOD and TSS. The non-compliance with the pH of the effluent was a temporary side-effect associated with operations of the new wastewater treatment facilities. Connaught Laboratories and TSI-GSD intend to reduce the levels of copper, lead and mercury in wastewater entering and leaving the wastewater treatment plant prior to the effective date of the more stringent NPDES standards. These efforts are reflected in the significant reduction in copper concentrations of the effluent recently reported by Connaught Laboratories (Appendix M). There is no evidence that aquatic life in Swiftwater Creek has been significantly impacted by the effluent discharged from the Connaught Laboratories wastewater Treatment plant (see Section 5.2.1) or by the contribution of TSI-GSD to the effluent discharge.

It is highly unlikely that infectious organisms would be released in the effluent of the Connaught treatment plant. Liquid infectious waste is autoclaved prior to entering the sterilization tanks. Accidental release of infectious material to the sterilization tanks is prevented by the absence of floor drains in laboratories. No potentially infectious liquid waste can be discharged from TSI-GSD to the Treatment plant prior to completion of the sterilization cycle (see Sections 2.3.2.2 and 2.3.2.4). The mechanical duty cycle (steam heating of wastewater at 226 degrees Fahrenheit for at least six hours) must be completed before water can be released to the Connaught Laboratories wastewater treatment plant. Ozonation provides supplemental disinfection in addition to the sterilization achieved by steam heating to the TSI-GSD effluent (Gaudy and Gaudy, 1980).

Floodway Boundary and Floodway Maps for Monroe County indicate that TSI-GSD is situated outside the 100 year floodplain of Swiftwater Creek (U.S. Department of Urban Development, 1983). No significant environmental impacts to Swiftwater Creek from TSI-GSD would be anticipated under most flood conditions since potential floodwater would not come into contact with the TSI-GSD facility.

Although TSI-GSD utilizes groundwater for routine operations, wastewater is disposed of through the Connaught Laboratories treatment plant. Consequently, there are no negative impacts to groundwater arising from TSI-GSD operations.

5 2.2 Land Quality

There are no serious impacts of TSI-GSD activities on land use. Activities are being conducted within existing facilities, no construction is proposed, and no existing environments are being adversely affected or altered. TSI-GSD land use patterns conform to the current and planned development within Monroe County and are consistent with municipal zoning restrictions of Pocono Township (Pocono Township Ordinance Number 16, Pocono Township Ordinance Number 34).

A small negative impact to soil erosion from landfill operations may be expected from the contribution of TSI-GSD to the Grand Central Sanitary Landfill in Northampton County. Included in the waste accepted by the landfill is a variety of municipal, residential and industrial waste. The Grand Central Sanitary Landfill does not accept hazardous waste materials and each industrial waste stream accepted must receive prior approval. The solid waste contributed to this landfill by TSI-GSD consists of an average of 25 pounds of incinerator ash (approximately one half a ton per year) and 10 cubic yards of compacted waste basket trash per week (approximately 100 tons per year). The Grand Central Sanitary Landfill is permitted to receive up to 1,500 tons of waste per day (Hassinger, 1992). For the period October 1990 to September 1991 the Grand Central Sanitary Landfill received 437,648 tons of waste (Tritt, 1992). Potential soil erosion and the volume of the waste contributed by TSI-GSD are negligible.

5.2.3 Air Quality

TSI-GSD does not have any significant adverse impacts on air quality because TSI-GSD emissions are relatively small (see Section 4.15) and appropriate safeguards are in place to prevent significant adverse impacts.

There is a minor impact on the ambient air quality arising from the electrical energy required for the operation/maintenance of TSI-GSD and vehicle emissions from the work force due to commuting. Consumption of electrical energy by TSI-GSD indirectly contributes to adverse air quality because fossil fuels are used to generate electricity. However, the consumption of electricity by TSI-GSD is a negligible component of the total electrical consumption of the Monroe County region. Another source of adverse air emissions into the environment is the vehicular emissions from the motorized traffic associated with TSI-GSD. TSI-GSD is the destination of approximately 70 passenger vehicles daily; these are a minor component of the traffic 90w in the immediate vicinity of TSI-GSD. TSI-GSD total traffic flow is less than one percent of the daily traffic flow in the vicinity of TSI-GSD. Their effects on local and regional air quality are insignificant.

There is a potential for low level impact to air quality due to the discharge of formaldehyde gas used in decontamination procedures (see Section 2.3.2.1). Use of formaldehyde gas is considered to be an effective decontamination procedure for large laboratory areas and air handling systems (Appendix 13, BDRP, 1989; Deforrest, 1983). As detailed in Append* D, the concentration of formaldehyde gas is estimated to be diluted to 0.06 ppm after being exhausted from TSI-GSD. For comparative purposes, the permissible occupational exposure to formaldehyde gas is 0.75 ppm as a 8-hour timeweighted average (29 CFR Part 1910.1048). Atmospheric circulation would immediately reduce the formaldehyde concentration below 0.06 ppm (see Appendix D). The frequency of use of formaldehyde gas at TSI-GSD averages once a month. Potential adverse effects on human health and the environment are thus negligible.

The incinerator at TSI-GSD contributes to air emissions through waste stream management activities. The incinerator is rated to handle 75 pounds of waste per hour. On average, the incinerator is operated 2.25 times per week Approximately 370 pounds of waste material consisting of used animal bedding, animal carcasses and any solid waste containing potentially infectious material is burned per week of operation.

The PADER requires that ash from pathological waste incinerators receive an annual chemical analysis due to its designation as a special handling waste. This testing is required prior to initial acceptance into the landfill and annually thereafter. Analysis of the microbiological characteristics (presence *of* aerobic and anaerobic organisms) is required on a quarterly basis. TSI-GSD is in compliance with these requirements (see Section 23.2.3). Air emissions from the pathological waste incinerator are not an area of significant concern Incineration activities are in compliance with regulations of the Commonwealth of Pennsylvania In addition, the operating temperature and the types of materials burned in the incinerator result in small amounts of emissions to the atmosphere (see Section 2.3.2.3)

Transiently offensive odors may originate from sterilization practices at TSI-GSD. The production of vaccines and diagnostics at TSI-GSD requires that considerable material, including contaminated laboratory materials, animal remains and wastewater be rendered sterile through the use of heat treatment and incineration (see Sections 2.3.2.2, 2.3.2.3, 2.3.2.4). These odors are minor and localized, and are rapidly dispersed in the atmosphere. Moreover, these odors are a necessary result of procedures used to control and contain infectious material. PADER requires that incinerators with odor problems raise temperatures above 1,200 degrees Fahrenheit (Pennsylvania Code; Title 25, Part I, Subpart C, Article III, Chapter 123, Section 123.31). The TSI-GSD incinerator temperature (1,500 degrees Fahrenheit) efficiently destroys most odors (see Section 2.3.2.3). There are no reports of citizen complaints describing excessive odors associated with the TSI-GSD/Connaught Laboratories complex (see Section 4.1.12).

5.2.4 Plant and Animal Ecology

There is minimal potential for adverse impacts to either critical habitats or species of special concern by TSI-GSD operation. No state or federally endangered/threatened species are known to inhabit or frequent this area of Monroe County (see Section 4.1.2; Appendix I). Moreover, the general alteration of the natural habitat along the Route 611 corridor suggests this area is poorly suited for species of special concern.

There are no detectable impacts to wildlife and vegetation by operations at TSI-GSD. Federal or state endangered/threatened species or species of special concern are not present on TSI-GSD grounds or in the general region around Swiftwater (see Section 4.1.2; Appendix I). Consequently, TSI-GSD does not exert a negative impact on special status plants and/or animals.

Activities conducted at TSI-GSD are consistent with the industrial zoning classification of Pocono Township and planning policies of Monroe County (see Section 4.1.1). The soils and ecological habitat of the area are not significantly impacted by routine operations. The facility is not situated on a wetland nor does it lie within the 100 year floodplain of Swiftwater Creek (see Sections 4.1.2 and 5.2.1). Protected habitats such as wetlands near TSI-GSD and Swiftwater Creek are thus unaffected.

Discharges of gaseous and liquid wastes and disposal of solid wastes originating from TSI-GSD are in compliance with state and federal regulations (see Sections 2.3.2.2, 2.3.2.3, 2.3.3.3, 2.3.3.4, 2.3.2.5) and are unlikely to adversely affect native plants and animals (see Section 5.2.1). Appropriate water quality standards for the protection of aquatic life are not usually exceeded by treated sewage discharged from the Connaught Laboratories wastewater treatment plant (see Section 5.2.1). Consequently, the recreationally-important fishery of Swiftwater Creek is not adversely impacted by routine activities of TSI-GSD as indicated by water quality data (Table 5-1) and maintenance of the *HQ-CWF* classification by the Commonwealth of Pennsylvania (Pennsylvania Code; Title 25, Part I, Subpart C, Article II, Chapter 93). There are no records of fish kills or harm to other aquatic life in Swiftwater Creek attributable to normal discharges from the Connaught Laboratories wastewater treatment plant. Recent modifications to the wastewater treatment plant will further reduce the potential for any adverse ecological effects associated with the discharge.

5.2.5 Human Health and Safety

5.2.5.1 Public Health and Safety

Risk to the health of people outside TSI-GSD is negligible. Release of infectious biological agents from TSI-GSD is prevented by sterilization of all liquid and solid wastes and HEPA filtration of air prior to discharge to the environment (see Sections 2.3.1.1, 2.3.2.2, 2.3.2.3, 2.3.2.4). Although certain citizens feel a degree of risk is associated with waste stream management, there have been no reports nor verified claims of releases of infectious materials or chemicals to the outside environment. Escape of infected insects or rodents is unlikely from BL-3 laboratories (CDC, 1988). Insecticides are applied to the facility monthly by a commercial pest exterminator. There have been no records of infected rodents or insects escaping from TSI-GSD. Building design features are consistent with CDC/NIH guidelines to prevent escape from or entry into the facility by insects and rodents (see Appendix 9, BDRP FPEIS; CDC, 1988). No person outside of any Army medical biological production or research laboratory is known to have become infected from substances originating from these facilities, including TSI-GSD (French, 1991), in over 40 years of operation (see Appendix 8, BDRP FPEIS).

An analysis of the history of laboratories working with infectious biological agents concluded that there was minimal likelihood of disease occurring in the general populace as the result of laboratory activities (see Appendix 8, BDRP FPEIS). The potential for disease originating from laboratory quantities of infectious agents in populations outside facilities such as TSI-GSD is small (see Appendices 8 and 9, BDRP FPEIS). This analysis indicated very little possibility for either an individual outside the facility to acquire disease or for human-to-human transmissibility (see Appendices 7 and 8, BDRP FPEIS). It is unlikely that a person outside TSI-GSD could contract a disease from an infected worker because human-to-human transmissibility is low for the particular biological agents used at TSI-GSD (see Appendix 7, BDRP FPEIS). The normal epidemiological pathways for the infectious agents used in the BDRP including TSI-GSD require insect vectors or are transmitted from non-primate animals to man. Thus, the natural mode of transmission for these agents is not from human-to-human (see Appendices 7 and 9, BDRP FPEIS). The current activities and historical safety record of TSI-GSD are consistent with this conclusion (see Section 5.3).

Public health and safety are enhanced by operations at TSI-GSD because vaccine and diagnostic products manufactured at the facility may be used against disease organisms naturally present in the environment (see Section 1.1). Members of the public and military both may potentially benefit from the work conducted at TSI-GSD (see Section 5.2.6).

5.2.5.2 TSI-GSD Worker Health and Safety

The laboratory work force involved directly with high-hazard organisms at TSI-GSD is at the greatest risk of laboratory acquired infection (see Appendix 8, BDRP FPEIS). The actual risk is small and is further ameliorated by redundant safety equipment, procedures and immunizations (see Section 2.0 and below). The ascribed versus the actual risks to laboratory personnel are largely ones of perception. Some members of the public perceive the work force is at greater risk than suggested by historical evidence. A lack of documentable, significant negative impacts implies that risks for the occupational safety and health of the laboratory work force are negligible (see Section 5.3).

Appropriate engineering controls, SOPs, and administrative actions have been implemented to reduce and minimize risk to personnel. All activities are performed in compliance with federal, state, and CDC/NIH guidelines and regulations (see Section 2.0; CDC, 1988). Regulations promulgated for worker safety by various federal and state agencies are complied within the conduct of routine operations at TSI-GSD. These requirements are included in the relevant portions of Army Regulations, USAMRDC regulations, contract clauses, OSHA and CDC/NIH guidelines and in institutional SOPs (see Section 2.3.2).

The historical safety record of TSI-GSD supports the conclusions drawn above. There has been one incident involving two employees with symptomatic cases of a laboratory-acquired infectious disease (Q fever) in the 29 years of operation at this facility (including the corporate predecessors to TSI-GSD). One individual was hospitalized and the second employee consulted with a physician. However, this is a treatable disease and there were no serious consequences. There have been no cases of the infection of family members of workers or people not employed at TSI-GSD (French, 1991). Employee awareness, strict compliance with health and safety SOPs, and use of the appropriate biocontainment facilities have contributed to the low incidence of laboratory-related illnesses in the TSI-GSD work force.

An approximation of the probability of a TSI-GSD laboratory worker contracting a symptomatic infection can be obtained based on the historical safety record of the facility. Currently 48 individuals are involved in at-risk activities which support the following estimates of probability. Employment at TSI-GSD has increased from approximately 22 in 1980 to 50 in 1984 and is 82 in 1992. Assuming 60 percent of the staff are involved in laboratory at-risk positions (48 of the 82 staff members presently) and an average total work force of 50 for the ten year period (30 laboratory employees), it can be estimated that approximately 600,000 people-hours have been worked during the time period (30 people x 10 years x 2,000 people hours/year). Using the two cases mentioned previously, the incidence of laboratory workers acquiring symptomatic infections at TSI-GSD are: 2 infections/600,000 people-hours (or 3.3 infections/l,000,000 people-hours) worked for this time period. The actual incidence is lower since the above calculation does not include the two years TSI-GSD was in operation with a small work force prior to 1980.

5.2.6 Social and Economic Environment

TSI-GSD activities and waste stream management may slightly alter the aesthetic character of the local area. Generation of odors is associated with incineration operations (see Section 23.23) but the transient nature of these odors does not cause a significant environmental impact (see Section 4.1.12).

Noise levels in the vicinity are not significantly impacted by operation of TSI-GSD. Vehicular traffic, predominantly passenger vehicles, generates noise at TSI-GSD and off-site. Maintenance activities (e.g. transportation of supplies, disposal of wastes) also will not significantly increase the noise level surrounding TSI-GSD. In general, TSI-GSD is quiet. There are no records of citizen complaints of excessive or objectional noise from routine TSI-GSD operations (see Section 4.1.11).

There are no projected impacts on cultural resources since operations are being conducted within existing facilities, no construction is proposed, and no existing environments are being adversely affected or altered (see Section 4.0).

TSI-GSD employs 82 people, 69 of whom reside in Monroe County. These employees represent approximately 0.07 percent of the population of Monroe County. The current monthly payroll is approximately $230,000 which represents approximately 0.4 percent of the total county payroll.

On average, TSI-GSD spends $65,000 per month on supplies purchased mostly through local vendors. Operating expenses average $54,000 per month and include taxes and services for telephone, electricity, repair and maintenance. Approximately $75,000 per month is expended on services purchased from Connaught Laboratories such as medical support, building security and sewage treatment facilities. Although most of the TSI-GSD work force resides in Monroe County, this labor force does not have a significant economic impact on the local community (see Sections 4.1.13.1 and 4.1.13.2).

Some individuals and special interest groups view development and production activities involving GEMs and high-hazard microorganisms negatively. These activities remain controversial (see Appendices 6 and 10, BDRP FPEIS). Controversial aspects of these activities are unrelated specifically to the operations of TSI-GSD but are better described as programmatic issues. Section 5 2 of the BDRP FPEIS addresses and details these concerns. Government facilities, including those supported by the BDRP, do not engage in work related to the production or use of offensive biological agents or toxins as defined by the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Biological Weapons Convention of 1972). The U.S. is a signatory to the Biological Weapons Convention of 1972.

Several benefits are realized from the continuance of operations at TSI-GSD. The primary benefit is the contribution of vaccine production efforts to U.S. national defense. Production of vaccines and other prophylactic measures against biological weapons is believed to be the major deterrent to their development or use by potential adversaries of the U.S. Furthermore, disease agents under study at TSI-GSD are naturally present in the environment, including portions of the U.S. (see Appendix 7, BDRP FPEIS). Therefore, the diseases caused by these agents remain a concern for both exposed civilians or military personnel who may be called to serve in various parts of the world. In addition, vaccine production at TSI-GSD contributes to disease prevention.

The activities of TSI-GSD have numerous positive impacts in the fields of defense, biosafety, microbiology and human health. Included among the products of the TSI-GSD are vaccines against Western equine encephalitis, Eastern equine encephalitis, Venezuelan equine encephalomyelitis, Rift Valley fever, *Coxiella burnetii* (Q fever) rickettsia, and *Francisella tularensis* (tularemia) bacteria.

The activities of TSI-GSD also contribute to the scientific community at large. Through their activities as consultants and their participation in the greater scientific community, TSI-GSD scientists share their experiences and expertise with industrial and pharmaceutical laboratories, as well as with other U.S. and foreign agencies. The staff of TSI-GSD are considered experts in biological containment, biosafety and vaccine production.

5.3 Accident and Incidents

Hypothetical releases of biological aerosols or infected rodents have been evaluated previously in Appendix 9 of the BDRP FPEIS which discussed Maximum Credible Events (MCEs) under various scenarios. MCEs are considered worst case events which realistically might occur, although the probability of such events is very low. These hypothetical events represent the most severe circumstances. The TSI-GSD is a typical site for execution of BDRP activities involving *High Hazard Organisms (see* Appendices 4 and 5, BDRP FPEIS). The activities, procedures, and operations used in handling the biological agents at TSI-GSD are consistent with those examined in the BDRP FPEIS (see Appendices 4 and 5, BDRP FPEIS; Section 2.0). Releases of these agents were viewed to be both improbable and unlikely to negatively impact the public. Multiple, redundant containment barriers, controls, and procedures are utilized during operations at TSI-GSD involving high-hazard organisms, and meet or exceed guidelines and regulations for work with BL-3 organisms. Members of the work force are immunized against infectious organisms whenever immunizations are available (see Sections 2.3.2 and 2.3.2.1; CDC, 1988). Detailed examination of the safety record of TSI-GSD supports conclusions that current safeguards and practices are sufficient to maintain work force and environmental safety in the BL-3 laboratories of BDRP (see Appendix 8, BDRP FPEIS).

There was one incident in September 1991 associated with the Connaught Laboratories wastewater treatment plant which resulted in a direct negative impact to Swiftwater Creek. In this event, a bulldozer operator inadvertently severed a stand-pipe in the settling pond. Approximately 30,000 gallons of chlorinated (8 ppm) water were discharged to Swiftwater Creek and caused the deaths of approximately 20 game fish. The chlorinated water escaped into the creek before Connaught Laboratories could take corrective or mitigative action. Connaught Laboratories replaced the fish and paid a $13,800 fine to PADER. This fine covered both the accidental spill of chlorine and all noncompliance episodes for the last four years. An electrofishing survey conducted on June 16, 1992 for PADER in Swiftwater Creek near the discharge of the Connaught Laboratories wastewater treatment plant indicated an abundant population of young of the year fish (Kirby, 1992b). The presence of such organisms indicates that no lasting impact to Swiftwater Creek resulted from the unusual chlorine accident. There is no chance of such an event reoccurring because Connaught Laboratories has eliminated the use of chlorine in its wastewater treatment plant. This incident was not directly related to operations of TSI-GSD.

5.3.1. Accidental Release or Escape of Biological Materials

The BDRP FPEIS (Appendix 9) provided an evaluation of the potential threat to the environment and humans (work force and general public) associated with the hypothetical release of Q fever and Rift Valley fever virus. Although infectious *High Hazard* agents in addition to Q fever and Rift Valley fever virus are used at TSI-GSD (see Section 2.2; Appendix 4, BDRP FPEIS), an analysis limited to the examination of the potential impacts resulting from the accidental release of these two agents adequately addresses the risks associated with an accident or incident. This is because Q fever and Rift Valley fever viruses are representative of the high risk (BL-3) agents used at TSI-GSD and possess characteristics typical of all Risk/Issue Category I, High Hazard Organisms, that TSI-GSD utilizes. Biological agents classified as requiring BL-3 have similar virulence, pathogenicity and communicability and are most likely spread by the aerosol route (see Appendix 4, BDRP FPEIS). The scenarios analyzed in Appendix 9, BDRP FPEIS, identified no credible evidence of risk to the environment under routine conditions. Minimal risk was associated with work place exposure. The group of individuals who were at the greatest risk were laboratory personnel in close -contact with high-hazard organisms (see Section 5.2.5.2). Non-laboratory workers were not demonstrated to be at any significant risk.

Environmental control of biological air quality by HEPA filtration during routine operations is described in the CDC/NIH guidelines (CDC, 1988), in the BDRP FPEIS, Appendix 12 and in Section 2.3.2.1 of this document. There is no evidence that infectious biological material has been ventilated by TSI-GSD to the outside environment. The BDRP FPEIS described the physical dynamics and dispersion models for biological agents used at BDRP facilities (see Appendix 9, BDRP FPEIS). The BDRP FPEIS evaluated MCEs for aerosol exposure to two agents used at TSI-GSD - Q fever and Rift Valley fever. The maximum spread of airborne hazardous materials during an accident is calculated to remain within the walls of TSI-GSD buildings due to the state-of-the-art containment systems, biological safety cabinets, HEPA filters, and the limited quantities of hazardous materials on site (see Appendix 9, BDRP FPEIS). Conditions at TSI-GSD meet or are less extreme than these situations. Therefore, no new calculations are needed for TSI-GSD. Infectious organisms are handled at the appropriate levels of safety and containment meeting or exceeding all federal, state and local regulations and guidelines (see Sections 2.3.2 and 2.3.2.1; CDC, 1988).

It is unlikely that native plant or wildlife species would be negatively affected by releases of infectious biological materials from TSI-GSD. During routine operations there are no releases of infectious biological waste. Survivability of infectious agents or infected laboratory animals would be small if they escaped from the facility (see Section 5.3.2). Moreover, there is no evidence that infectious biological agents have been released by TSI-GSD to the environment.

The likelihood of escape and survival of infectious agents outside of a facility such as TSI-GSD has been previously considered using MCE methodologies in the BDRP FPEIS (see Appendix 9, BDRP FPEIS). No evidence is available indicating that infectious organisms have escaped outside TSI-GSD. Consequently, it is unlikely that native wildlife have been deleteriously affected by TSI-GSD operations. The organisms used at TSI-GSD are not infectious to plants (see Appendix 7, BDRP FPEIS). In addition, no plant pathogens are utilized at TSI-GSD.

5.3.2 Other Possible Modes of Release of Organisms

The BDRP FPEIS (Appendix 9) examined other possible modes of release of organisms from BL-3 facilities. The assumptions and conclusions of the BDRP FPEIS are valid for TSI-GSD activities since operations, procedures and agents used at TSI-GSD are consistent with or less extreme than the MCEs evaluated in that document. Scenarios in which infectious organisms might be potentially released from TSI-GSD include external events such as airplane crashes, bombs, tornadoes, and floods. For a large external release of an infectious agent to occur, a series of catastrophic failures in multiple containment barriers must occur. External events such as airplane crashes and tornadoes might allow all levels of containment to be breached; however, they would simultaneously create an inhospitable environment for the infectious agent. The natural environment for the infectious agents used at TSI-GSD is within vectors and host organisms. Atmospheric characteristics such as relative humidity, temperature and solar radiation stress infectious agents and destroy or reduce their ability to survive and subsequently infect humans (see Appendix 7 BDRP FPEIS; Block, 1983). Such events would rapidly kill organisms and/or dilute the concentrations of the agent below those considered necessary for infection (see Appendices 7 and 8, BDRP FPEIS).

The total amount of infectious material at TSI-GSD is small in aggregate. Generation of an aerosol containing infectious agents and sufficient to cause infection is improbable since the majority of the particles originating from these hypothetical external events would be in the form of droplets and would quickly settle. In the event of an explosion or other external force which would generate any aerosol material, time and distance limitations would rapidly reduce the concentration of infectious agent.

In the event that an infected animal did escape from the facility or that a large quantity of infectious material was emitted to the environment, very low rates of survivability of infected animals and infectious organisms suggests limited environmental impacts. Additionally, rapid changes in atmospheric humidity and the presence of ultraviolet radiation from the sun would further decrease survival of the organisms. Animal-to-animal and human-to-human transmissibility of these agents is poor. In addition, if laboratory animals did surmount all levels of containment and escape outside the facility, their survivability would be small due to such factors as starvation and predation.

5.4 Cumulative Impacts

Analysis of the TSI-GSD operations supports the conclusion that there are no negative cumulative impacts to the environment associated with those operations of TSI-GSD. Minor areas of concern were identified and included potential negative impacts to health and safety of the work force, water quality of Swiftwater Creek, biological air quality, and solid and liquid waste disposal. However, upon close examination, no significant impacts to the surrounding environment are attributable to the combined past, continuing, and future operations of TSI-GSD.

Vaccine production work has been performed at this geographical site for approximately 100 years with no appreciable negative impacts to either the work force or the environment. An active production program of vaccines, diagnostics and related supporting activities has been conducted at TSI-GSD facilities since 1962 with no significant adverse environmental impacts. All relevant state and federal regulations governing air, water and solid waste discharges are complied with by TSI-GSD (see Sections 2.3.2.2, 2.3.23, 4.1.4, 4.1.5). There is no reason, based on an analysis of TSI-GSD activities in the context of the environmental setting, to indicate that any significant negative cumulative impacts arise from the ongoing work at TSI-GSD.

Positive impacts were identified for social and economic portions of the environment (see Section 5.2.6). There are no known cultural impacts. Cumulative impacts to these environmental components are not anticipated to have negative consequences. The combined effects of TSI-GSD with other businesses located in the area (e.g., Connaught Laboratories) have been evaluated and no synergistic effect to the air (see Section 5.2.3), water (see Section 5.2.1) land (see Section 5.2.2) ecological (see Section 5.2.4) or other environmental component has been observed.

Although the effluent from the Connaught Laboratories wastewater treatment plant is unlikely to be toxic to aquatic life in Swiftwater Creek, a small negative impact would likely be associated with bioaccumulation of mercury in the tissues of organisms at locations downstream from the Connaught Laboratories wastewater treatment plant (Wetzel, 1975).

Routine operations at TSI-GSD do not result in significant impacts to air and water quality in the immediate area, nor do they affect land use patterns (see Sections 4.1.1, 4.1.5). Monroe County lacks major industrial activities and as a result general air quality is good (see Section 4.1.5). The collective odors of TSI-GSD and Connaught Laboratories do not significantly affect the surrounding area. Laboratory emissions from TSI-GSD are HEPA-filtered to reduce potential discharge of biological materials to the environment (see Section 2.3.2.1). Relatively small quantities of waste formaldehyde gas are emitted to the atmosphere on an infrequent basis but are rapidly diluted to very low concentrations (see Sections 2.3.2.1, 5.2.3, Appendix D). Air pollution associated with commuting activities of the work force is negligible since the transportation corridors to TSI-GSD are moderately utilized by other sectors of the population (see Section 5.2.3). A small cumulative effect to locations downstream from the TSI-GSD/Connaught Laboratories area of Swiftwater Creek resulting from the mercury concentrations in the effluent discharge has been identified. Swiftwater Greek maintains the *HQ-CWF* water classification for the Commonwealth of Pennsylvania (see Section 5.2.1). Laboratory wastewater is sterilized before leaving the facility (see Section 2.3.2.2). There is no evidence that the quantities of chemical and biological waste products emitted from TSI-GSD have resulted in or will cause significant cumulative impacts to the environment. Cumulative effects of the operation of TSI-GSD have been observed, evaluated and do not result in significant adverse impacts to the environment.

5.5 Comparison of the Proposed Action and the Other Alternatives

5.5.1 Alternative I - Transfer the USAMRDC Sponsored Work at TSI-GSD to Another Location

Most of the potential impacts associated with BDRP activities, to include those conducted at TSI-GSD, were determined in the BDRP FPEIS to be primarily site independent, i.e. the site where a particular activity is conducted is less important than the conduct of the activity itself. As stated in Section 2.2.3, work with high hazard agents conducted at TSI-GSD corresponds to the *High Hazard Organism* risk/issue category evaluated in the BDRP FPEIS. With appropriate controls in place (see Section 6.4, BDRP FPEIS) e.g., operational, safety, etc., the activity can be conducted without significant adverse impact to the environment. The assumptions and conclusions of the BDRP FPEIS are valid for TSI-GSD since the facility is a typical site in the context of the BDRP FPEIS (see Appendix 5, BDRP FPEIS). Furthermore, BDRP and IDRP protocols apply parallel methods and safety/containment procedures. The risk/issue categories apply equally to the work sponsored by both of these programs. These assumptions and conclusions concerning BDRP sponsored activities at TSI-GSD are equally valid for IDRP sponsored activities at this site. For example, assumptions and conclusions concerning the *High Hazard Organism* risk/issue category for BDRP sponsored work are equally applicable to IDRP sponsored work with this category of organisms. It is the nature of the work and not the source of funding, or benefited program, that is environmentally important.

Construction of a new facility at another location or renovation of an existing facility have the potential for negative impacts on the environment as a result of the construction efforts. Doing the same work that TSI-GSD is currently doing at another location would require the same controls and regulatory compliance (see Section 6.0, BDRP FPEIS); the net result is envisioned to be the same; i.e., potential minor adverse impacts on health of the work force and no significant adverse effects on the human environment. Moving the work conducted at TSI-GSD to a more industrial and/or urban setting would be less desirable because combined impacts may be unacceptable (see Section 5.4). This alternative is not envisioned to have any beneficial environmental effect over the preferred alternative.

5.5.2 Alternative II - No Action Alternative

Because TSI-GSD is a functioning organization, the alternative of "no action" would be to cease the activities presently supported under the USAMRDC contract with TSI-GSD. This action would cause the discontinuation of a significant part of the medical BDRP and IDRP.

This "no action" alternative was discussed in Section 4.3 of the BDRP FPEIS, under the consideration of termination of the BDRP. This alternative would seriously impair the national defense posture with respect to medical countermeasures to biological warfare threats as well as to naturally occurring diseases of military importance. This is specifically true of TSI-GSD because it is a major site for vaccine production activities. Because no significant adverse environmental effects have been identified with the BDRP as it is conducted at TSI-GSD, closure of TSI-GSD would neither significantly reduce adverse impacts nor produce significant environmental effects.

5.5.3 Alternative III - Continue the Operation at TSI-GSD in its Present Scope

This alternative includes the continued conduct of the medical portion of the BDRP and other high and low hazard infectious disease work (IDRP) and the operation of TSI-GSD as a vaccine production facility. Given that the continued requirement for the BDRP and infectious disease work is established by the DoD and the programs are authorized by Congress, the preferred alternative, in the context of the medical portion of the BDRP and the IDRP, is the continued operation of TSI-GSD as a vaccine production facility. The environmental consequences of all types of activities conducted at TSI-GSD, given the appropriate biosafety facilities, equipment and practices, as well as security and other operational and regulatory controls, have been considered in this EA and found to be insignificant.

TSI-GSD is one of the individual sites analyzed in the BDRP FPEIS, and no significant environmental effects from the conduct of the BDRP were identified. The current and planned activities conducted at TSI-GSD are consistent with the conclusions of the BDRP FPEIS. Implementation of this alternative involves the continuation of tangible but minor adverse impacts, such as contributions to the waste stream and small risks to the health of the work force. Existing controls, which are continually upgraded as improved technologies become available, further reduce these impacts. Implementation of this alternative also involves the continuation of program benefits, e.g., contributions to national defense and to the scientific community, as discussed in Section 15 of the BDRP FPEIS.

6.0 CONCLUSIONS

The proposed action of continuing operation of TSI-GSD in its present scope will have no significant adverse environmental impact and will result in important benefits to the country and the world. Routine operation of TSI-GSD is safe and poses no significant threat to the environment. Risks to the environment associated with accidental release of dangerous substances or hazardous organisms are extremely small. Benefits of continued operation far outweigh the risks.

The most severe potential effects envisioned are minor, and all actually observed effects are insignificant. Vaccine production activities have been conducted at this location for nearly 100 years and the environmental quality of the area remains good. Detailed analyses of the individual TSI-GSD activities and impacts, as well as the actual cumulative impacts of operations by TSI-GSD, Connaught Laboratories, Inc. and others in the immediate vicinity of TSI-GSD did not reveal any significant environmental impacts. Therefore, individual and cumulative impacts of TSI-GSD operations are minor.

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7.0 REFERENCES

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APPENDIX A
BDRP ACTIVITIES AND CONTROLS
TAKEN FROM THE BDRP FPEIS, SECTIONS 3.1 - 3.5

3. DESCRIPTION OF THE PROPOSED ACTION

3.1 INTRODUCTION

In section 2, the BDRP was defined from the perspectives of the mission objectives, program management, and sites of program execution. The proposed action under consideration in this DEIS is the continuation of the BDRP. The purpose of this DEIS is to identify and evaluate potential environmental impacts that might arise from the proposed action, and to consider reasonable alternatives. To this end, the BDRP was subdivided into discrete, functional activities that could be evaluated individually for their potential impacts. Activities intrinsic to the conduct of research, development, test and evaluation, as well as activities intrinsic to program administration and management, were identified and are discussed below.

Program activities are conducted in the context of numerous operational, safety, security and regulatory controls. These controls, in essence, define the "normal operating conditions" of program activities. The program activities and their associated controls are an integral part of the Impact Analysis Matrix (IAM) (see Appendix 6), an analytical tool developed specifically for the identification of the potential environmental impacts of the BDRP. Although this FEIS evaluates a program, the program only has physical reality in the sites or facilities at which it is conducted. Thus, the primary and representative secondary sites of program execution were identified. The potential impacts of program activities as executed at various sites were-evaluated by using the IAM. In addition, the potential impacts of program activities conducted in support of particular programmatic subject areas, the "Risk or Issue Categories," were analyzed similarly.

The program activities, controls, facilities and programmatic areas that constitute the BDRP are described here.

3.2 TYPES OF ACTIVITIES

3.2.1 RESEARCH, DEVELOPMENT, TEST AND EVALUATION

3.2.1.1 Laboratory Support Work

"Laboratory work" includes the handling of supplies and materials that are not unique to the particular subject of study in a given laboratory. This handling of supplies and materials, such as plasticware glassware, non-hazardous chemicals and reagents, etc., is generally considered to be of very low intrinsic risk. The preparation of common reagents and solutions, such as culture media, buffer solutions, etc., is included in this activity. The maintenance of laboratory equipment either within a general use laboratory, or after appropriate decontamination and removal from a biosafety level 3 or 4 laboratory, is also included in this activity.

3.2.1.2 Storage of Chemicals, Biologicals, Supplies and Radioisotopes

Storage refers to the storage and maintenance of all laboratory supplies and materials in a BDRP facility. For items presenting little or no potential safety or environmental hazards, e.g. glassware, plasticware spare parts, etc., ordinary storage units and practices are employed. Specific storage procedures and requirements are employed for particular classes of chemicals, such as heavy metal salts, acids, bases, organics, and chemicals subject to regulation as hazardous materials or RCRA hazardous wastes. Storage units, procedures, and practices for biological materials are tailored to requirements for maintenance of biological activity of the material in question, as well as to the biohazard classification of the material (30) . The small quantities of radioisotopes used in BDRP studies are stored in a manner that will preserve the biological activity of the labeled compounds, as well as meet NRC regulatory requirements for storage and handling of radioisotopes.

3.2.1.3 Conduct RDT&E-Specific Procedures

This activity includes all use and handling of EDRP-specific microorganisms and toxins, from removal from storage through performance of experimental or test procedures, decontamination of the spent materials, the equipment and/or laboratory, and disposal of the biological materials. The transportation of biological materials into and out of the facility is included inthis activity, because the special requirements fortransportation of biohazardous organisms and toxins parallel the requirements governing their use in a laboratory.

3.2.1.4 Laboratory Animal Care and Use

This activity is segregated from the "Procedures" activity because the use of animals in biomedical research has been identified by the public as a controversial issue in and of itself, if not in relation to the BDRP This activity includes all aspects of the use of laboratory animals in BDRP research and testing. The identifiable phases of laboratory animal use are: receipt and holding of animals, assessment of the health status of the animals, caging, feeding and watering of animals, use of the animals in experimental or test protocols, and disposal of animal remains and bedding.

3.2.1.5 Prototype Development of RDT&E Materials

A prototype is an operational model suitable for evaluation of the design, performance, or production potential of a particular item. The activity described here is the development of prototypes of all RDT&E materials related to the BDRP This includes the development, for the purpose of protection from biological threat agents, of personal protective equipment, such as masks, and development of detector systems for identification of biological agent threats. The development of protective vaccines or immunogens, and development of potential therapeutic drugs is also included in this activity.

3.2.1.6 Testing

Developmental testing of BDRP prototype materials is described by this activity. The biological material prototypes, such as vaccines, are tested in human volunteers. Such testing is conducted in full compliance with FDA and DA regulations governing the participation of human subjects in medical research. Equipment prototypes are tested within laboratory chambers for performance to operational specifications. Detection and personal protection equipment prototypes may be tested, as required, at the DPG in open-air tests with nonhazardous, non-toxic, biological simulants.

3.2.2 ADMINISTRATION AND MANAGEMENT

3.2.2.1 Facilities Operations and Maintenance

This activity includes operation, maintenance, and repair of all facility systems such as water, wastewater, steam, electrical, telephone, heating and air conditioning. Routine structural repairs and maintenance of the building and its grounds, including routine cleaning, are included. The operation and maintenance activities for facility operations within the BDRP are similar to common practices employed throughout the commercial and industrial medical field.

3.2.2.2 Waste Stream Management

This activity includes the management, treatment, control, and monitoring of effluents resulting from BDRP activities, regardless of source. Effluent air includes exhausts from buildings, laboratories, biosafety cabinets, heating, and incinerator discharge stacks. Management, control, treatment and monitoring of sanitary wastewater and contaminated laboratory wastes are included in this activity. Handling, storage, and disposal of liquid hazardous and toxic material are included as well. Liquid hazardous or toxic materials are as designated by the various states and by the U.S. Environmental Protection Agency. Sanitary wastewater includes general wastewater and non- laboratory wastewater. Contaminated laboratory wastewater results from procedures involving toxins or hazardous organisms, and includes shower, lavatory, and floor drain discharges from maximum containment laboratories. Management of the solid waste stream includes the handling, storage and disposal of refuse and discarded solid wastes generated by BDRP RDT&E activities. Discarded solid wastes include supplies, materials, chemicals, equipment, and animal wastes. Biohazardous wastes are decontaminated or detoxified before entry into the waste stream.

3.2.2.3. Planning and Designing Systems

This activity describes those BDRP efforts that involve the preparation of test methods for equipment, and the preparation of test methods for biological and biomedical research. It includes the planning and design of experimental and test methodologies for medical and physical protective systems as well as the overall planning of a project at the program task and sub-task levels. General planning activities include paperwork, idea formation, and activities requiring mental effort on the part of the professional staff.

3.2.2.4. Program Management

Activities in this category include management, accountability, and projection of the BDRP budget; administration of personnel and program activities; and review, analysis and planning of program objectives to achieve mission objectives. The primary sites are responsible for program management and implementation with respect to the secondary sites Thus, an additional program management activity of primary sites is the administration of contracts and other instruments used to support the secondary sites. Program management includes administrative decision-making as it specifically applies to RDT&E operations and program development. The publication of program accomplishments and results in specialty publications, as well as in public documents, e.g. the Congressional Descriptive Summary, is identified as a program management activity.

3.3 CONTROLS

At least four major classes of controls govern the conceptual and physical conduct of activities comprising the RP. These operational, safety, security, and regulatory controls, described below, ensure the safe handling of potentially hazardous biological materials as well as compliance with federal, state and local laws, regulations and policies. The descriptions of these controls are not necessarily comprehensive, but are intended to indicate some of the types of controls in effect throughout every aspect of the BDRP.

3.3.1 OPERATIONAL

3.3.1.1 Physical Plant: The physical plant provides an important secondary barrier for protection of the environment from potentially hazardous biological materials used within a facility. Primary protective barriers are used within the individual laboratories and are addressed in the Safety section. The operational features of the physical plant that provides protection to the environment (both internal and external) include: air handling systems appropriate to the levels of the potential biological hazards used in the facility; emergency power backup systems that would serve to maintain equipment serving primary barrier functions during a power failure; and the overall engineering of the facility, e.g. placement of air intakes and exhausts, adequacy of power systems, isolation of laboratory vacuum lines from other aspects of the air system, traps in the drainage systems, etc. Recommendations for the design of biological containment laboratories for biohazard levels 3 and 4 work are specified in detail in the publication "Biosafety in Microbiological and Biomedical Laboratories" (5). The most important features of containment laboratory design are the provision for controlled access, specialized ventilation systems, and sealed openings into the laboratory. The specialized ventilation systems maintain laboratory air pressure negative to the immediate surroundings (i.e., air flow is into the laboratory rather than out of it), the exhaust air from the laboratory (BL-4) is filtered through HEPA filters or incinerated, and alarm systems provide immediate notification if air handling systems malfunction. Routine surveillance and maintenance of the facility's systems, and testing of backup systems, are required for effective functioning of the physical plant as a secondary barrier (see Appendix 12).

3.3.1.2 Waste Stream: Management of the solid and liquid waste streams in accordance with RCRA, Clean Air and Water Acts, and federal, state, and local standards is critical to protection of the environment. State or local governments often require that research and development facilities secure separate permits or certifications for discharge of their liquid and solid wastes. At a minimum, potentially hazardous laboratory wastes are segregated from sanitary waste to allow appropriate monitoring of the laboratory wastes. For work with biological materials that pose potential hazards to the environment, both solid and liquid laboratory wastes are routinely pretreated to render them nonhazardous. Pretreatment methods include autoclaving of solid and/or liquid wastes to heat-inactivate biologically hazardous materials, and chemical inactivation of liquid wastes (with appropriate subsequent consideration of disposal of the chemical agents used for decontamination). Monitoring and testing of pretreated wastes serve to assure that they have been rendered nonhazardous. Depending on the location of a given facility, laboratory solid wastes are disposed of either by incineration or burial in landfill (for disposal of certain materials, pathological incinerators, or hazardous materials landfills) operating under appropriate permits or licensure.

3.3.2 SAFETY

Since the preparation of the DEIS, the Director of Defense Research and Engineering issued a policy on DoD research activities in the BDRP This policy formalized the requirement that all efforts in the BDRP be conducted in compliance with the CDC-NIH Guidelines: *Biosafety in Microbiological and Biomedical Laboratories,* and further established the requirement that compliance with this guideline be included as a prerequisite in BDRP contracts. The USAMRDC, the only component of the BDRP supporting work at secondary sites that requires the use of BL-3 or BL-4 laboratories, has implemented the DoD directive by establishing formal requirements in contracts for compliance with the Guidelines as well as for pre-award and post-award laboratory inspections.

The Army has initiated efforts to clearly identify the Army Safety Office, a subordinate function of the Office of the Chief of Staff, as the focal point for safety in the BDRP. In order to clarify and codify the responsibilities for safety throughout the program, the Army Safety Office has drafted two documents: an Army regulation on "The Army Biological Defense Safety Program," and a supporting Army Pamphlet that provides the technical information necessary for conduct of the safety program. The regulation will go into effect after formal review and approval.

3.3.2.1 Regulations: Numerous national and state regulations on the safe handling of specific hazardous materials apply to the BDRP. Occupational Safety and Health Administration (OSHA) regulations (29 CFR) apply primarily to employee safety with regard to ambient air quality and presence of toxic and/or carcinogenic materials. NIH Guidelines for Research Involving Recombinant DNA Molecules (31) have the force of law when the work conducted is supported by NIH funds. The DoD voluntarily adopted and mandated compliance with the NIH guidelines for all DoD-sponsored activities (DoD laboratories as well as contractors) involving genetic engineering (32). The Nuclear Regulatory Commission (10 CFR Ch. 1) regulates the use, handling and disposal of radioactive materials (primarily compounds containing very low energy isotopes) used in the BDRP. U.S. Food and Drug Administration guidelines and regulations (21 CFR) (for example, "Good Laboratory Practices") apply to research conducted in support of application for licensure of new drugs, vaccines or pharmaceuticals. The U.S. Department of Agriculture regulates the importation, possession, and use of animal and plant pathogens under authority of the Virus-Serum-Toxin Act-(21 USC 151-158). The EPA, under the Toxic Substances Control Act, has ruled that genetically engineered microorganisms are chemical substances subject to the provisions of that Act for the purposes of manufacture, public distribution or significant new use. Other public laws and federal regulations govern the participation of human volunteers in biomedical research.

3.3.2.2 Institutional Approval: Certain institutional approval authorities are mandated by policy or regulation. These include, for example, an Institutional Biosafety Committee for review of research *using* recombinant DNA, and Radiation Safety Committees for review and approval of use of radioisotopes in biomedical research. Additional institutional approval authorities include committees governing the use of laboratory animals in research and research using human volunteers. The Institutional Biosafety Committees often have an extended mandate to review and approve all institutional research involving potentially hazardous chemicals, organisms or toxins. Frequently, two separate biosafety and/or health and safety committees oversee recombinant DNA work and other work involving biohazardous materials, respectively. Periodic laboratory inspections for compliance with various regulations are conducted by internal or external reviewers, depending on the subject of the inspection. It should be noted that funding authorities, such as the NIH DA, National Science Foundation, and numerous other private foundations that support biomedical research, all require requests for research support to be formally approved by authorized institutional officials. If work with animals, recombinant DNA, humans, or radioisotopes is involved, documentation of appropriate approvals must also be provided before any funds are awarded. Questions as to suitability of facilities or personnel are resolved by site visits prior to the award of funds.

3.3.2.3 Professional Standards: Professional standards and guidelines for the safe conduct of biomedical research are promulgated by various agencies and organizations. Examples of such standards are the NIH Laboratory Safety Monograph (33) and the CDC-NIH publication "Biosafety in Microbiological Laboratories" (5). Specialized areas in which individuals and/or laboratories must receive certifications before performing in a professional capacity include clinical laboratory technology, pathology, radiology, etc. In addition, many professional societies offer training courses and guidance in technical standards that are readily available to researchers at all levels. At the institutional level, compulsory employee orientations, provision of safety handbooks, and training in the use of isotopes, animals, specialized equipment, biosafety procedures, and emergency responses serve to promulgate and reinforce safe laboratory practices. On-the-job training of individuals involved in research and implementation of local standard operating procedures facilitate the maintenance and dissemination of professional standards. As appropriate to the level of biohazard work being conducted, worker protection is furthered by the provision of laboratory garments (lab coats, scrub suits, etc.), gloves, masks, respirators, and equipment (for example, automatic pipettors) designed to isolate the worker from the biological materials. Work conducted at the BL-3 or BL-4 level is conducted in a laboratory specifically designed and equipped to meet those biosafety standards (5). Thus, while there is no single codified set of professional standards applicable to the conduct of research in the BDRP, many specialized standards for the use of infectious organisms, and performance of various laboratory techniques and procedural methods exist and are accepted and followed throughout the biomedical research community.

3.3.2.4 Laboratory Design and Practices: The CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories" (5) describes combinations of standard and special microbiological practices, safety equipment and facilities that constitute Biosafety Levels 1-4 (BL 1-4), which are recommended for working with a variety of infectious agents in various laboratory settings (see Appendix 12). Two elements of containment for infectious agents are described. Primary containment, which is designed to protect personnel and the immediate laboratory environment, includes use of good microbiologist technique, i.e. maintenance of sterility and reduction of incidental aerosols, and use of appropriate safety equipment, e.g. Biosafety cabinets (see Appendix 11), sealed and vented centrifuges, etc. Secondary containment, designed to protect the environment external to the laboratory from biohazardous organisms, is provided by facility engineering features and operational practices.

In addition to these Biosafety guidelines, the Laboratory Safety Monograph (33) published by the NIH as a supplement to the NIH Guidelines for Recombinant DNA Research (34) describes detailed relevant laboratory practices, containment equipment, special laboratory design and roles and responsibilities. The guidelines for detailed laboratory practices include selection of laboratory techniques for biohazard control, personal hygiene habits and practices, protective clothing and equipment, housekeeping, decontamination and disposal, care and use of laboratory animals, and protection of vacuum systems when filtering biohazardous materials. The detailed descriptions of containment equipment include selection of biological safety cabinets and certification procedures. The details of special laboratory design include specifications for BL3 and BL4 facilities and their certification procedures. The roles and responsibilities section includes guidelines for the institutional biosafety committee, the biological safety officer, emergency procedures, medical surveillance, and training aids, materials and courses. A book in preparation by the National Academy of Sciences, National Research Council titled "Biosafety in the Laboratory: Prudent Practices for the Handling and Disposal of Infectious Materials" presents comprehensive guidelines covering all facets of the operation of a laboratory in which human pathogens are handled. This peer-reviewed treatise incorporates the CDC-NIH guidelines and extends the recommendations in the Laboratory Safety Monograph (33) to all activities that involve infectious organisms other than those specifically involving recombinant DNA.

While the guidelines described above apply to work performed with infectious organisms, no similar set of national guidelines yet exists for the handling of toxins of biological origin. Standard Operating Procedures are developed locally for the handling, use and disposal of toxins, as appropriate. However, guidelines for the safe handling of botulinum toxin and the organism that produces it, *Clostridium botulinum,* are specifically described in the CDC-NIH Biosafety guide (5). (Recommended containment levels are BL-2 or BL-3 depending upon amounts of material used and specific procedures performed.) Because botulinum toxin is one of the most potent of the known biological toxins, the principles of good laboratory biosafety and containment described for this toxin serve as good guidelines for laboratory work with other equally or less potent toxins.

3.3.2.5 Good Judgement: The essence of good judgement in any research activity is the protection of oneself, others in the laboratory, the environment (both internal and external), and lastly, the experimental material. Indeed, researchers and other laboratory personnel have a vested interest in their own health and safety. As a rule of thumb, when there is uncertainty as to the appropriate level of protective measures for a given situation, the highest available level of primary protective barrier is employed. An example of implementation of this policy is handling of a potentially hazardous blood sample in a biosafety cabinet while wearing surgical gloves, rather than handling such material on an open bench with bare hands. Good judgement extends also to conscious efforts to minimize the potential for accidents, and seeking guidance from standards or experts when confronted with unusual situations.

3.3.3 SECURITY

3.3.3.1 Laws and Regulations: Depending upon the location and ownership of a given facility, local, state and/or federal laws govern the security of that property. These laws and regulations pertain to trespass of unauthorized individuals, physical damage to property, theft of property, and violation of the owner's rights. Laws and regulations typically allow property owners to bar the general public from unauthorized entry to a facility and to place physical barriers for prevention of entry.

3.3.3.2 Enforcement: Depending upon jurisdiction, local, state or federal law enforcement officials uphold and execute the laws pertaining to property security for a given facility. In addition, personnel employed in a facility are charged with the responsibility to notify appropriate officials if they observe violations of relevant laws.

3.3.3.3 Physical security: Several levels of physical security, although implemented primarily to enhance property security, contribute to the overall safety of the BDRP. Many facilities have perimeter controls, where public access is regulated through manned gates. Facility doors are locked after working hours, on holidays, and weekends. Doors to laboratories are similarly locked during non-working periods. Biologically hazardous materials are stored in appropriate units (cabinets, refrigerators, freezers) to which access is controlled by a system of locks. Many facilities have implemented, or plan to implement, personnel access controls in the form of computer- facility access systems (such as magnetic card key systems), which only permit passage of an employee to designated areas, and further, provide an alarm system and audit trail for monitoring access violations. Guidelines for BL-3 and BL-4 laboratory operations contain additional specifications on control of access to the laboratory and access to hazardous infectious organisms (see Appendix 12).

3.3.4 REGULATORY CONTROLS

3.3.4.1 Controlled and Hazardous Substances: Federal regulations and common carrier tariffs have been enacted to ensure the safe transport of hazardous biological materials. U.S. Public Health Service (USPHS) regulations (42 CFR 72) specify packaging and labeling requirements for etiologic agents see Appendix 2). The U.S. Department of Transportation (D.O.T.) regulations (49 CFR 173) contain additional requirements for packaging, and the U.S. Department of Agriculture (USDA) regulates animal (and plant) pathogens (9 CFR 122). The U.S. Food and Drug Administration (FDA) regulates the use, handling and shipment of biological products (21 CFR 312 and 600-800). In addition, U.S. Dept. of Justice, Drug Enforcement Administration, regulations (21 CFR Ch. II) list four classes of controlled substances for which use licenses are required, and to which specific DOT regulations apply.

3.3.4.2 Congressional: The U.S. Congress, through the budget authorization and appropriations process, controls all funds used to support the BDRP (see section 2.3 for discussion of program elements, projects, and tasks). An annual report on Chemical Warfare - Biological Defense Research Program Obligations is presented to Congress at the end of each fiscal year. In addition, an annual Research, Development, Test and Evaluation (RDT&E) Congressional Descriptive Summary, covering the various RDT&E DoD mission areas, is presented. The BDRP is identified discretely in the RDT&E achievements and fiscal analyses that are presented in this latter report.

3.3.4.3 National Policy and the Biological Weapons Convention: The U. S. formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in National Security Decision 35, November 25, 1969 In National Security Decision 44, dated February 20, 1970, the U.S. renounced "offensive preparations for the use of toxins as a method of warfare," and reiterated that "the U.S. will confine its military programs for toxins, whether produced by bacteriological or any other biological method or by chemical synthesis, to research for defensive purposes only, such as to improve techniques of immunization and medical therapy." In 1972, the U.S. signed the Biological Weapons Convention (Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction). Appendix 1 contains excerpts of these documents. The U.S. Senate ratified the Biological Weapons Convention in 1975. The BDRP is conducted in full cognizance of and compliance with these national policies and the BWC.

3.3.4.4 Army Regulations: Army Regulations (ARs) provide specific guidance and implementation of applicable federal regulations, public laws, and DoD policies. In addition to ARs, numerous technical bulletins and local implementations of ARs provide guidance on specific policies and procedures. Two major groupings of Army regulations (ARs) contain individual regulations that govern, in whole or in part, various aspects of the BDRP. The two major M series are Medical Services (AR 40 series) and Research, Development, and Acquisition (AR 70 series). The most important regulations from these two series, as well as miscellaneous pertinent regulations, are listed below.

AR 40 Series - Medical Services

40-1	Composition, Mission and Functions of the Army Medical Department
40-7	Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances
40-10	Health Hazard Assessment Program in Support of the Materiel Acquisition Decision Process
40-12	Medical and Agricultural Foreign and Domestic Quarantine Regulation for Vessels, Aircraft and Other Transports of Armed Forces.
40-14	Control and Recording Procedures for Exposure to Ionizing Radiation and Radioactive Materials
40-24	Medical Laboratory Activities
40-38	Clinical Investigation Program
40-56	Introduction Requirements Determination and Publication of New Type Classified Medical Items Into the Department of Defense
40-60	Policies and Procedures for the Acquisition of Medical Materiel
40-61	Medical Logistics Policies and Procedures AR 70 Series - Research, Development and Acquisition

AR 70 Series - Research, Development and Acquisition

70-1	Systems Acquisition Policy and Procedure
70-5	Grants to Nonprofit Organizations for Support of Scientific Research
70-6	Management of the Research, Development, Test and Evaluation Army Appropriation

70-10	Test and Evaluation During Development and Acquisition of Materiel
70-11	Dissemination of Scientific and Technical Information
70-14	Publication and Reprints of Articles in Professional Journals.
70-17	System, Program, Project, Product Management
70-18	The Use of Animals in DoD Programs
70-25	Use of Volunteers as Subjects of Research
70-26	Department of the Army Sponsorship of Unclassified Scientific or Technical Meetings
70-35	Advanced Planning Information for Research and Development
70-59	Department of Defense Tactical Shelter Program
70-65	Management of Controlled Substances, Ethyl Alcohol and Hazardous Biological Substances in Army Research, Development, Test and Evaluation Facilities.
70-69	Major Range and Test Facility Base
70-71	Nuclear, Biological and Chemical Contamination Survivability of Army Materiel
70-72	Production Management
70-74	Independent Research and Development Miscellaneous

Miscellaneous

AR 190-50	Physical Security for Storage of Controlled Medical Substances and Other Medically Sensitive Items
AR 190-51	Security of Army Property at Unit and Installation Level
AR 190-52	Countering Terrorism and Other Major Disruptions on Military Installations
AR 385-10	Army Safety Program
AR 385-40	Accident Reporting and Records
AR 740-32	Responsibilities for Technical Escort of Dangerous Materials

3.4 FACILITIES SUPPORTING THE BDRP

3.4.1 Primary Sites

The primary DA sites at which BDRP activities are conducted are described in section 5.2.2 and Appendix 5. The RDT&E activities associated with the Program are conducted in specific laboratory facilities at each of these sites. Depending upon the types of microorganisms or toxins used, and the nature of the research or testing conducted, the individual facilities are specially designed and equipped to meet the biosafety level standards described in Appendix 12. For example, USAMRIID, the lead laboratory for medical defensive studies, contains laboratories designed and equipped at biosafety levels 1 through 4. The nature of the BDRP activities conducted by CRDEC requires laboratories that function only at biosafety levels 1 and 2. The Baker Laboratory Complex, DPG, currently performs laboratory developmental testing studies that require only biosafety level 2 facilities. The outdoor grid testing areas at DPG are used in tests with simulants in support of the BDRP only in response to specific materiel developer requirements, and only after preparation of appropriate NEPA documentation.

3.4.2 Secondary Sites

Representative secondary sites where BDRP studies are conducted are described in sections 5.2.3 and Appendix 5. Appendix 3 lists all secondary sites supported by the BDRP, current as of January 1, 88. Secondary sites supported by the BDRP all contain existing facilities appropriate for the particular BDRP studies conducted at that site. As a general policy, the BDRP does not support the construction of new facilities at secondary sites. Laboratory operations are conducted by established organizations within enclosed facilities where all waste streams are managed in compliance with existing laws and regulations. The majority of secondary sites provide only general laboratory facilities, where studies of microorganisms or toxins requiring only biosafety levels 1 or 2 containment are conducted. A small number of secondary sites provide biosafety level laboratory facilities for performance of BDRP-supported studies.

3.5 POTENTIAL RISK/ISSUE CATEGORIES

The BDRP can be subdivided into several subject area categories relating to identifiable potential risks to the health and safety of the workforce or the environment, as well as to areas of public controversy. This programmatic perspective provides a useful and realistic basis for the analysis of potential impacts on the environment that might arise from the BDRP. A detailed discussion of each risk/issue category is presented in Appendix 4, and BDRP sites were identified according to these categories (by corresponding Roman numeral) in Appendix 3.

Many of the BDRP research and development efforts are similar, or parallel, to research and development efforts conducted in universities and research institutes throughout the U.S. and in other countries. At the level of the most basic research efforts, BDRP research is virtually indistinguishable from that conducted and sponsored by the National Science Foundation, National Institutes of Health (NIH), and the Centers for Disease Control (CDC). It is only when the research effort is carried into the phase of product development (e.g., vaccines, detectors) that the effort can be identified as one that is clearly of less general interest to the civilian sector than to the DoD. Nonetheless, both civilian and military biomedical product development involve the use of similar laboratory techniques and materials, including organisms, toxins, genetically engineered microorganisms (GEMs), etc. The general procedures, risks safeguards, and potential environmental consequences are the same, regardless of the organization sponsoring the effort.

The NIH developed guidelines (34) for recombinant DNA research under the auspices of the National Environmental Policy Act (NEPA) (7,35) and other federal statutes. These guidelines established the minimum standards for laboratory safety,including procedures, equipment, and facilities appropriate for safe conduct of recombinant DNA research (33). The guidelines have been modified over the past decade (37-39) to reflect research experience and public input, which are incorporated in the most recent guidelines, published May 7, 1986 (31). The NIH and CDC jointly published guidelines that detail the laboratory procedures, safety equipment, and facilities design required for the safe conduct of research with pathogenic organisms (5). The DoD implementations of the NIH and CDC guidelines require laboratory procedures and containment facilities that meet or exceed these federal standards (32).

The most probable biological warfare threat to U.S. forces is an attack with aerosols of biological agents. Thus, the BDRP efforts differ from those conducted by most non-DoD organizations in the requirement for the use of aerosol challenges in the preclinical phase of vaccine and drug development, or aerosol testing in the development of protection, detection and decontamination systems. In the civilian sector, aerosol test systems are used primarily in the study of communicable diseases transmitted by the aerosol route, such as influenza, and in the development of aerosol forms of therapeutic drugs, for example, various aerosol asthma therapies and aerosol Virazole for treatment of respiratory syncytial virus infection in infants.

3.5.1 High Biohazard Organisms (I)

This subject category includes all laboratory activities with organisms for which biosafety levels 3 and 4 containment are recommended by the CDC-NIH guidelines (5). In addition, for laboratory procedures with BL-2 organisms that pose potentially greater risks to workers or the environment, e.g. possible generation of aerosols or use of highly concentrated preparations of organisms, the next higher biosafety level, BL-3, from that generally recommended for a particular organism is used and given consideration in this category.

3.5.2 Genetically Engineered Microorganisms (GEMs) (II)

GEMs do not constitute a programmatically defined category per se because genetic engineering is not a discrete object of study, but rather is considered a state of the art tool to be applied to attaining specific research objectives. This topic is given separate identification here primarily because of the public perception of special environmental risks associated with GEMs. In addition. segments of the BDRP can be identified as including, or potentially including, use of genetic engineering or genetically engineered microorganisms in the research and development endeavor. The NIB has published an environmental impact statement (7,35,37,38) specifically addressing the issue of GEMs and research involving recombinant DNA molecules. Thus, the analysis of the potential impact of GEMs and their associated methodologies on the environment presented in this DEIS is restricted to the context of the BDRP

3.5.3 Toxins (III)

This category includes all toxins, as well as potentially toxic substances of biological origin such as bioregulators. Laboratory work with toxins may pose risks to an exposed individual, but unlike infectious microorganisms, toxins are not living entities and do not propagate themselves in a host or in the environment. Although there are no nationally recommended biosafety levels for work with toxins per se, the CDC-NIH guidelines (5) recommend biosafety level 2 for most work conducted with *Clostridium botulinum* the bacterium that produces the potent botulinum neurotoxin. In addition, appendix F of the NIH Guidelines for Research Involving Recombinant DNA Molecules (31) addresses the appropriate levels of biosafety for use in cloning toxic molecule genes. For the most potent classes of toxins, biosafety levels 2 or 3 are recommended, depending upon the biological containment (host-vector) system used. Unless there are procedures that would pose an increased risk to the laboratory worker, such as potential for creation of aerosols or work with highly concentrated materials, work with toxins is appropriately conducted at biosafety level 2 (see Appendix 12). In the case of procedures with toxins or toxic molecules requiring more stringent containment measures and higher biosafety levels, consideration was given in the analysis under the high hazard organisms category.

3.5.4 Low Hazard Organisms (IV)

This subject area includes all low hazard organisms, which are defined by the CDC as including a broad spectrum of indigenous microorganisms present in the community and associated with human disease of varying severity (e.g., communicable diseases), as well as organisms present in the environment and not known to cause disease in healthy adult humans (5). By definition, the low hazard organisms pose far less potential risk to the workforce and to the environment than the high hazard organisms. Organisms in this category are incorporated into the program whenever and wherever they can be used and still give meaningful results. Organisms used as simulants in testing of physical protective devices belong to this category.

3.5.5 Rapid Diagnosis and Detection (V)

This subject area was defined separately because it is a major identifiable program area that is of overall low-risk potential to either human health or the environment. The development and design of detection equipment, development of assay systems, and associated use of non-hazardous and non-toxic biological materials are considered in this category. Where development of reagents for testing of products and/or equipment would involve use of infectious agents or toxins, the analysis of environmental impact for this subject area was considered under those higher risk categories as appropriate.

3.5.6 Vaccine and Drug Therapy Development (VI)

This subject area is a major identifiable element of the BDRP in which the potential risks or impacts are of a markedly different nature than those evaluated under the high-hazard organisms or toxin categories. This subject area includes only the preclinical and clinical testing of anti-agent drugs, i.e. antiviral drugs, anti-toxin drugs, and vaccines. The other research and development aspects of drug and vaccine development involving use of infectious agents or toxins are covered under one or more of the other subject area risk categories.

Phase III human clinical testing of drugs or vaccines is conducted only where and when a target disease occurs naturally. Such human testing is conducted under appropriate controlled conditions meeting the human testing standards of the United States and of the country in which a study may be conducted. There is no introduction of an agent into the environment, and no additional risk to human or environmental health and safety over that which is a result of the occurrence of natural, endemic disease.

3.5.7 Other Program Research and Activities (VII)

This category includes those areas of the program that do not appropriately fit into one or more of the categories defined in sections 3.5.1-6, and that are likely to have imperceptible, if any, impact on the human or natural environment, and do not constitute discrete subject areas warranting separate consideration. Examples of these sorts of activities are literature studies, purification of immune plasma, and handling of non-hazardous biological laboratory materials.

APPENDIX B
ANALYSIS OF PROGRAMMATIC RISK/ISSUES
TAKEN FROM THE BDRP FPEIS, APPENDIX 4

APPENDIX 4 - ANALYSIS OF PROGRAMMATIC RISKS/ISSUES

CONTENTS

SECTION

1. High hazard organisms

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4. Low hazard organisms

5. Rapid diagnosis and detection

6. Vaccine and drug therapy development

7. Other program research and development activities

1. High Hazard Organisms

1.1 Introduction

A number of factors influence the determination of an appropriate biosafety level for work with a particular organism. Among the factors that must be considered for a given organism are: virulence, pathogenicity, biological stability, route of spread, communicability, nature or function of the laboratory, the procedures and manipulations involving the organism, quantity and concentration of the organism, endemicity of the agent, and availability of effective vaccines or therapeutic measures.

The assignment of microorganisms to the category requiring BL-3 practices, safety equipment, and facilities is based on one of the following criteria, as stated in the CDC-NIH guide (1) overt laboratory-associated infections have occurred by aerosol route if protective vaccines are not used or are unavailable: or laboratory experience with the organism is inadequate to assess risk and the natural disease in humans is potentially severe, life threatening, or causes residual damage. Similarly, the assignment of an organism to the category of agents requiring BL-4 containment is based on documented cases of severe and frequently fatal naturally occurring human infections and aerosol-transmitted laboratory infections.

The data upon which these classifications of organisms are based were accrued over years of operation of microbiological research and clinical laboratories throughout the world. Since the early 1900's, reports of laboratory-acquired infections have been published in the biomedical literature. Several systematic surveys of laboratory-acquired infections have been conducted in the past 40 years. Efforts initiated under the auspices of the World Health Organization in the late 1950's to codify the taxonomic relationships of the.arthropod-borne viruses resulted in the ongoing publication of the "International Catalog of Arboviruses Including Certain Other Viruses of Vertebrates" by The American Society of Tropical Medicine and Hygiene (ASTMH). This Catalog provides descriptions of those viruses biologically transmitted by arthropods in nature (or thought originally to be transmitted by arthropods), and actually or potentially infectious for humans or domestic animals. A subcommittee of ASTMH, the Subcommittee on Arbovirus Laboratory Safety (SALS), assessed documented arbovirus infections of laboratory workers. In 1990, SALS published recommended levels of practices and containment for all viruses listed at that time in the Catalog (2). The SALS committee activities are ongoing; information on newly discovered viruses is evaluated so that appropriate biosafety levels for work with those viruses can be determined.

Certain bacteria and rickettsia are classified as BL-3 or BL-4 organisms on the basis of criteria similar to those applied to viruses, i.e., known laboratory infections, infectivity by the aerosol route, stability, etc. For virtually all of the bacteria and rickettsia of interest in the BDRP, BL-2 containment and practices are recommended for handling quantities on the order of those used in routine clinical diagnostic procedures. However BL-3 containment, equipment, and practices are recommended for handling of the same organisms in procedures that potentially create aerosols, or when handling larger quantities.

The viruses, rickettsia, and bacteria used in the BDRP are capable of causing infections in humans, but these infections are not classified as communicable diseases because their natural mode of transmission is not from human to human (see Appendix 7). Representative organisms belonging to the groups classified as requiring BL-3 or BL-4 containment and procedures, for some of the types of procedures conducted with them in the BDRP, include the following:

Rickettsia:	*Coxiella burnetii* (Q fever
Bacteria:	*Francisella tularensis* (tularemia, "Rabbit fever") *Bacillus anthracis* (anthrax) *Clostridium botulinum* (produces botulinum toxin)
Viruses:	Chikungunya, tick-borne encephalitis, Hantaan, Rift Valley fever, Venezuelan equine encephalomyelitis, Yellow fever, Junin, Ebola, Crimean-Congo hemorrhagic fever, Lassa, Machupo.

1.2 Types of Studies Conducted Using High Hazard Organisms

Basic research studies of disease pathogenesis of both in vitro and animal models are conducted using the organisms described above. In addition, efforts to develop vaccines for these organisms range from basic research to human clinical trials of safety and efficacy. The development of antiviral drugs and therapies similarly involves studies from the basic research level through human clinical trials for efficacy in treatment of viral diseases. Laboratory testing of personal protective materiel, decontamination systems detector methodologies, and rapid identification and diagnosis methodologies requires the limited use of high hazard organisms to verify specificity.

1.3 Rationale for the Use of High Hazard Organisms in the BDRP

Because the primary concerns, from the standpoint of potential biological warfare threats, are organisms such as those listed above, and exposure by small particle aerosol, defensive research and development efforts must employ small quantities of the actual biological materials in order to develop and test the efficacy of vaccines, drugs, and therapies. A vaccine to a simulant or to a "model," low hazard organism or toxin would be of no value to the national defense posture. Similarly, the ability to detect or to protect against a harmless organism is of little value.

1.4 Environmental, Health and Safety Considerations

As required by the nature of the procedures being performed, studies of high-hazard organisms are conducted in BL-3 and BL-4 laboratory facilities, described in Appendix 12. These "maximum laboratory containment" facilities, equipment, and procedures are recommended in the CDC-NIH guide to biosafety (1), and are explicitly intended to provide protection to the laboratory worker as well as to the human environment in general.

The following vaccines are available (1) and are used to immunize at-risk laboratory personnel:

Q fever vaccine, tularemia vaccine, anthrax vaccine* , pentavalent botulinum toxoid (serotypes ABCDE), Rift Valley fever vaccine, Venezuelan equine encephalomyelitis vaccine (TC-83 and TC-84), Yellow fever vaccine* (17D), vaccinia*, tick-borne encephalitis.

Immune globulin, antibiotics, or antiviral drug treatments are available for use (1,4) in treatment of Q fever, tularemia, anthrax, botulinum intoxication, hemorrhagic fever with renal syndrome (caused by Hantaan virus), Junin hemorrhagic fever, and Lassa fever.

1.5 Waste Materials

A detailed description of the elaborate procedures required for removal and disposal of materials from BL-3 and BL-4 laboratories is presented in Appendix 12. All infectious or potentially infectious materials are killed by autoclaving prior to disposal. All residual botulinum toxin or toxin-containing materials are inactivated with alkali prior to disposal.

1.6 Security

Seed stocks or cultures of BL-3 and BL-4 organisms are stored in multi-walled, leak-proof containers in locked freezers which are in locked rooms located in locked biocontainment laboratories to which access, even to the outer room, is limited to authorized personnel. The security provisions for BL-3 and BL-4 laboratories, described in Appendix 12, apply to the general security for laboratory procedures with "working cultures" of the high hazard organisms.

* Licensed in the US. The other vaccines are available for use as Investigational New Drug (IND) products. Additional vaccines,e.g. Chikungunya (3), are in various stages of development.

1.7 Accidents and Incidents

Handling of highly infectious, pathogenic or exotic organisms always poses a potential risk to laboratory personnel. Thus, biosafety facilities, procedures and equipment, and vaccines, have been developed to minimize these risks. Since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BL-3 and BL-4 BDRP laboratory facilities, although in 1980, one focal infection with *F. tularensis* occurred at the site of a puncture wound. There have been laboratory accidents that resulted in potential exposures: however, prior immunization or immediate treatment with the appropriate therapy have averted the possible development of clinical disease (see Appendix 8). There have never been any occurrences of infections in non-laboratory workers or in the general community arising from organisms handled in BL-3 or BL-4 facilities associated with the BDRP.

1.8 Program Benefits

The development of vaccines, drug therapies, detector methodologies, and rapid identification and diagnosis methodologies for potential biological warfare threat agents s the national defense posture with respect to these threats Because many of the threat agents are also endemic disease hazards in certain areas of the world, the development of protective and therapeutic approaches for these diseases enhances the health status of peacetime forces stationed in such areas. For example, the development of an antiviral therapy for treatment of hemorrhagic fever with renal syndrome (Korean hemorrhagic fever), will potentially contribute significantly to the health and well-being of the local populace as well as to U.S. soldiers stationed in areas of the world where this disease is endemic. The results of the BDRP efforts with high-hazard infectious organisms contribute to a better understanding of the pathogenesis of many exotic diseases on the part of the general scientific community, and to the peoples living in areas of endemic disease caused by these organisms.

2. Genetically Engineered Microorganisms (GEMs)

2.1 Introduction

Genetically engineered microorganisms are derived in the laboratory by removing a fragment of genetic information, a gene, from one organism and "cloning" this fragment into another organism, called the host, which is usually a bacteria or yeast. Cloning refers to a sequence of steps in which the gene of interest is inserted, using special enzymes, into a special, non-chromosomal piece of DNA called a plasmid, or vector. The vector, containing the foreign gene, is introduced into the host cell. Plasmid vectors are not part of the host cell genetic information, but when the host cell divides, the plasmid divides also. Under ideal conditions, the foreign genetic information carried in the plasmid is then transcribed into RNA, translated into protein, and secreted from the host cell. Another approach is to clone gene fragments of interest into a vaccine virus. Commercial applications of genetic engineering have resulted in the production of biomedical products, such as the hepatitis B subunit vaccine, human growth factor, human insulin, tissue plasminogen activator (TPA), interferon, and diagnostic antibodies, as well a. veterinary and agricultural products, such as the swine pseudorabies vaccine and the frost-free *Pseudomonas* bacteria.

Because genes carry information which can be transcribed and expressed as a particular protein, only products that are protein in nature can be cloned. Thus, it is not currently possible to clone molecules that belong to other biochemical classes, such as steroids, alkaloids, fatty acids, carbohydrates, etc. These classes of compounds are synthesized in complex series of enzymatic reactions and are not simply the product of a single gene.

2.2 Types of Studies Conducted Using GEMs

Within the BDRP, genetic engineering is used in efforts to develop safer and more efficacious viral and bacterial vaccines as well as vaccines for protection against protein toxins, such as snake neurotoxins and botulinum neurotoxin. Through years of intensive effort, immunologists have discovered that antibodies, the molecules that fight infections and other foreign compounds introduced into the system, are extremely specific and can recognize even minute portions of a larger foreign molecule. Further studies have revealed that only small portions of the proteins on the surface of a virus, or small portions of a protein toxin, are necessary for the production of antibodies to that virus or toxin. Thus, vaccine development efforts focus on identification of those small portions of the viral, bacterial, or toxin proteins responsible for immunity, and on cloning those small immunogenic portions (these are called epitopes) in order to produce quantities that would be useful in the research, development, and testing of new vaccines. Another approach, also used in the BDRP is to clone the gene fragments coding for important epitopes into the vaccinia virus (smallpox vaccine virus) in the hope of developing a genetically engineered vaccinia vaccine that would confer immunity to two or more other viruses or toxins.

The following organisms and toxins are representative of the focus of BDRP efforts in genetically engineered vaccine development: Rift Valley fever virus, Lassa virus, lymphocytic choriomeningitis virus, yellow fever virus, anthrax (bacteria), botulinum toxin, crotoxin, staphylococcal enterotoxin.

2.3 Rationale for the Use of GEMs in the BDRP

Traditional vaccines used by both the military and civilian medical community fall into one of three categories: live, attentuated vaccines, killed organism vaccines, and inactivated toxin vaccines (toxoids). All three types of vaccines have intrinsic deficiencies. Live, attenuated vaccines cause an asymptomatic infection after administration, but for some vaccines, the rate of subacute and acute infection is undesirably high (e.g., influenza vaccines often produce a mild to serious flu-like syndrome in some recipients). Vaccines prepared from killed organisms often do not produce a highly effective immune response. Inactivated toxin vaccines, or toxoids, are generally prepared from crude materials and many of them are undesirably reactogenic, meaning that they produce local reactions such as swelling, redness, and soreness at the sit of injection. Thus, BDRP scientists use the modern approaches and techniques of genetic engineering in an effort to develop vaccines that obviate the difficulties and deficiencies of the traditional vaccines.

2.4 Environmental, Health, and Safety Considerations

The NIH, in the course of developing of the Guidelines for Research Involving Recombinant DNA Molecules (5,6), published an environmental impact statement (7) and environmental assessments (8) of the potential impacts of research with GEMs (see Appendix 10). In addition, the Recombinant Advisory Committee and other scientists have published documents dealing with risk assessment of the use of recombinant organisms. The conclusions of these assessments and studies are that genetic engineering techniques and GEMs, when utilized under the conditions recommended in the NIH guidelines, present no risk to the human environment. Appendix I of the NIB guidelines (6) describes the physical and biological containment levels recommended for use in recombinant DNA studies; these are also described in Appendix 10. Depending upon the nature of the gene being cloned, and the host-vector system employed, the recommended biocontainment levels for recombinant DNA work are either BL-2 or BL-3 These biosafety levels, discussed in Appendix 12, specify the laboratory facilities, procedures, and equipment appropriate for protection of laboratory workers and the environment from exposure to GEMs.

2.5 Waste Materials

A detailed description of the procedures required for removal and disposal of materials from BL-2 and BL-3 laboratories is presented in Appendix 12. All infectious or potentially infectious or toxic materials are killed by autoclaving or chemical inactivation prior to disposal.

2.6 Security

Seed stocks or cultures of BL-3 organisms used in BDRP studies involving genetic engineering are stored in multi-walled, leak-proof containers in locked freezers which are in locked rooms located in locked biocontainment laboratories to which access, even to the outer room, is limited to authorized personnel. The security provisions for BL-3 and BL-2 laboratories, described in Appendix 12, apply to the general security for laboratory procedures with "working cultures" of the high and low hazard infectious organisms.

2.7 Accidents and Incidents

Handling of highly infectious, pathogenic, or exotic organisms, including GEMs, always poses a potential risk to laboratory personnel. Thus, biosafety facilities, procedures, and equipment, and vaccines, have been developed to minimize these risks. Since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BL-2 and BL-3 BDRP laboratory facilities. Although in 1980, one focal infection with *F. tularensis* occurred at the site of a puncture wound. There have been laboratory accidents that resulted in potential exposures: however, prior immunization or immediate treatment with the appropriate therapy have averted the possible development of clinical disease (see Appendix 8). None of these potential exposures have involved GEMs. There have been no occurrences of infections or illness in non-laboratory workers or in the general community arising from infectious microorganisms, toxins or GEMs handled in BL-2 or BL-3 facilities.

2.8 Program Benefits

The development of vaccines effective against potential biological warfare threat agents enhances the national defense posture with respect to these threats. Because many of the threat agents are also endemic disease hazards in certain areas of the world, the development of improved protective vaccines through the use of genetic engineering potentially enhances the health status of peacetime forces stationed in such areas as well as that of the local population. The results of the BDRP efforts with GEMs contribute to the scientific community in the area of vaccine development in general, and specifically in the area of development of vaccines for and understanding the pathogenesis of exotic diseases or toxins.

3. Toxins

3.1 Introduction

The toxins studied in the BDRP are all derived from natural sources, and are thus designated "toxins of biological origin." Unlike many of the non-naturally occurring toxins, those that exist only as a result of chemical synthesis, the toxins of biological origin all exist in some ecological niche. In addition, these toxins are bioorganic molecules. Some are proteins or peptides others are small alkaloid-like molecules.

All are susceptible to degradation, denaturation or decay, whether within an organism or upon exposure to heat, acids, bases, enzymes or, in some cases, simple dilution. Laboratory work with toxins may pose risks to an individual who becomes exposed accidentally to toxic material, but unlike organisms, toxins are not living entities and do not propagate themselves in a host or in the environment. Thus, unlike disease-causing organisms, toxins cannot be transmitted from person-to-person (or animal or insect) (see Appendix 9).

3.2 Types of Studies Conducted Using Toxins

Various toxins are used throughout research, development, and testing activities. Studies conducted include basic research to elucidate the mechanism of action of a particular toxin, preparation of antibodies to a toxin, structural analyses to identify the parts of a toxin responsible for immunity, production of toxoids (inactivated toxins which are not toxic but can elicit an immune response) in support of vaccine development efforts, testing of decontaminants to determine efficacy against toxins, development and testing of methodologies with cellular receptors or antibodies for detection and identification of toxins, and testing of personal protective devices for effectiveness when exposed to toxins.

Representative toxins used in the BDRP include the following: botulinum toxin, anthrax toxin, staphylococcal enterotoxins, plant toxins such as ricin, toxins derived from snake and arachnid venoms, toxins produced by blue-green algae and other marine and fresh water organisms, tetrodotoxin, and trichothecene mycotoxins. Physiologically active compounds, particularly peptide hormones and neuromodulators, are included for consideration in the toxin category because excesses of these compounds can cause physiological imbalances similar to those caused by some toxins.

3.3 Rationale for the Use of Toxins in the BDRP

Toxins have traditionally been identified as significant biological threat agents (9) and thus are the focus of BDRP efforts to develop defensive measures such as vaccines, drugs, and protective materiel.

3.4 Environmental, Health and Safety Considerations

Because toxins are non-living and cannot establish themselves in the natural environment, they pose very little threat to the environment outside of the laboratory. BDRP laboratory worker. who handle anthrax or botulinum toxins (or the organisms that produce them) in quantities larger than those which would be encountered in a typical clinical or diagnostic laboratory are immunized with the appropriate toxoid (botulism) or vaccine (anthrax). Although there are no nationally recommended biosafety levels for work with toxins per se, the

CDC-NIH guidelines (1) recommend biosafety level 2 for work conducted with *Clostridium botulinum* the bacterium that produces the potent botulinum neurotoxin. In addition, appendix F of the NIH Guidelines for Research Involving Recombinant DNA Molecules (6) addresses the appropriate levels of biosafety for use in cloning toxic molecule genes. For the most potent classes of toxins, biosafety levels 2 or 3 are recommended, depending upon the biological containment (host-vector) system used (see Appendix 10). Unless there are procedures that would pose an increased risk to the laboratory worker, such as potential creation of aerosols or work with highly concentrated materials, work with toxins is appropriately conducted in biosafety level 2 laboratories.

3.5 Waste Materials

All laboratory materials containing or exposed to toxins are decontaminated, either chemically or with high heat, prior to disposal.

3.6 Security

Stock quantities of toxins are maintained in locked freezers or refrigerators. For those toxins that are studied within BL-3 laboratories, additional security is provided by the overall security provisions and access restrictions for such areas (see Appendix 12). Most of the toxins studied in the BDRP are available from commercial chemical/biochemical companies that sell research, diagnostic, and clinical reagents to biomedical laboratories. The quantities of any given toxin that are marketed and shipped are marked with appropriate warnings regarding potential biohazards, and are sold only to institutions which appropriately identify themselves as legitimate biomedical organizations.

3.7 Accidents and Incidents

The handling of toxins known to cause disorders in humans always poses a potential risk to laboratory personnel. These risks are minimized by the use of special biosafety facilities, equipment and procedures for those activities that would otherwise cause a high potential for exposure. In laboratories performing basic research studies with toxins, only minute quantities of a particular toxin are in use at any given time, and these small quantities pose virtually no risk to the laboratory workers. While some of the toxins studied, for example, botulinum toxin or tetrodotoxin, are sometimes lethal to man even with medical treatment, most of the toxicoses caused by other toxins can be treated successfully with supportive care and/or drugs which antagonize the action of the particular toxin.

There has been no occurrence in any laboratory worker associated with the BDRP of intoxication or poisoning as a result of handling toxins of biological origin.

3.8 Program Benefits

The development of vaccines and therapeutic drugs for potential biological warfare threat toxins enhances the national defense posture with respect to these threats. The basic research conducted to understand the mechanism of action of many of these toxins contributes to the general scientific community. Methods of detection developed for toxins of interest in the BDRP have many potential applications in the public health arena, where food borne toxins (such as saxitoxin, enterotoxins, botulinum toxin, mycotoxins) often cause serious economic and medical problems. It is of interest to note that one of the most potent toxins known to man, botulinum toxin, has been used successfully as a specific treatment for a disorder of the eye muscles known as blepharospasm. There are active efforts on the part of the biomedical community to develop methods for "targeting. toxins to cancerous cells and tumors, thus harnessing the potent toxicity of these materials for a positive effect.

4. Low Hazard Organisms

4.1 Introduction

The group of microorganisms designated "low hazard" by the CDC includes a broad spectrum of indigenous microorganisms present in the community and associated with human disease of varying severity (e.g., communicable diseases), as well as organisms present in the environment and not known to cause disease in healthy adult humans (1). By definition, the low hazard organisms pose far less potential risk to the workforce and to the environment than the high hazard organisms. Organisms in this category are incorporated into the program whenever they can be used and still give meaningful results. Organisms used as simulants in testing of physical protective devices belong to that class not known to cause disease in healthy adult humans. In addition, the live, attenuated vaccine strains of various hazardous viruses or bacteria are classified as low hazard organisms.

4.2 Types of Studies Conducted with Low Hazard Organisms

Basic research studies of disease pathogenesis using both in vitro and animal models are conducted with many of the low hazard organisms. Laboratory development and testing of personal protective materiel, detector methodologies, and rapid identification and diagnosis methodologies are most often conducted with the low hazard organisms. Clinical trials of live, attenuated vaccines or of the efficacy of an antiviral drug involve the use of low hazard organisms with human volunteers. Such clinical trials are conducted only after a thorough scientific and human use committee review and approval, and only under conditions of informed consent.

Representative low hazard organisms used in the BDRP are: Punta Toro virus, Pichinde virus, Dengue viruses, the live vaccine strains of yellow fever and Venezuelan equine encephalomyelitis viruses (17D and TC83, respectively), Sandfly fever virus, the live vaccine strain of *Franciscella tularensis,* and attenuated strains of *Bacillus anthracis.*

4.3 Rationale for the Use of Low Hazard Organisms in the BDRP

Low hazard organisms are used in BDRP research, development, and testing when the results obtained with such organisms will adequately address the questions posed. Development of experimental and test methodologies i. often performed with the low hazard organisms prior to testing with higher hazard organisms. The low hazard organisms require less rigorous containment facilities, equipment, and procedures than the high hazard organisms. Thus, their use allows for reservation of BL-3 or BL-4 facilities and equipment for appropriate uses. The low hazard organisms also, by definition, pose less risk to the workforce and environment, and thus are more safely handled by laboratory staff.

4.4 Environmental, Health and Safety Considerations

The low-hazard organisms are appropriately studied in BL-1 or BL-2 facilities. The recommendations that these organisms and/or strains can be studied safely at Biosafety Levels 1 or 2 are based on adequate historical laboratory experience which indicates that a) no overt laboratory-associated infections have been reported, or b) infections resulted from exposures other than to infectious aerosols, or c) if aerosol exposures are documented, they represent an uncommon route of exposure. It must be reiterated that many organisms that can be handled safely at BL-2 in small quantities by routine procedures still are classified as requiring BL-] facilities, equipment, and procedures for studies that involve handling of larger quantities of organisms or which potentially generate aerosols. In addition, it is recommended that laboratory workers be immunized with the live, attenuated vaccine strains such as TC-83 (VEE), 17D (yellow fever) or LVS (tularemia) when they are handling these organisms in BL-2 laboratories.

4.5 Waste Materials

Biological wastes of low hazard organisms are routinely killed, inactivated, or decontaminated either by autoclaving (high) temperature sterilization) or by chemical decontamination (bleach or Lysol solutions).

4.6 Security

The access restrictions for BL-1 and BL-2 laboratories are described in Appendix 12. Because the low hazard infectious organisms present only minimal risk to laboratory workers or to the environment, extraordinary security precautions are not warranted.

4.7 Accidents and Incidents

Handling of organisms capable of causing infections in humans always poses a potential risk to laboratory personnel. Thus, biosafety facilities, procedures, and equipment, and vaccines, have been developed to minimize these risks. Since 1971, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BL-1 and BL-2 BDRP laboratory facilities. There have been laboratory accidents which resulted in potential exposures; however, prior immunization or immediate treatment with the appropriate therapy have averted the possible development of clinical disease (see Appendix 8). There have never been any occurrences of infections in non-laboratory workers or in the general community arising from organisms handled in BL-1 or BL-2 facilities associated with the BDRP.

4.8 Program Benefits

The development of detector methodologies, rapid identification and diagnosis methodologies, and personal protective materiel for potential biological warfare threat agents enhances the national defense posture with respect to these threats. The results of the BDRP efforts with low hazard organisms contribute to a better understanding of the pathogenesis of many exotic diseases on the part of the general scientific community, and to the development of defensive methodologies and materiel.

5. Rapid Diagnosis and Detection

5.1 Introduction

The development of rapid diagnosis and detection methodologies and equipment is a major identifiable program area that is of overall low risk potential to human health and the environment. The development and design of detection equipment, development of assay systems, and associated use of non-hazardous and non-toxic biological materials is considered in this category.

5.2 Types of Studies Conducted for Rapid Diagnosis and Detection Efforts

Efforts conducted in support of development of rapid diagnosis procedures and detection equipment include the development of prototypes of assay systems, detection methodologies based on biological materials, and remote sensor detection equipment. In the development of assay systems and detection methodologies, efforts are directed toward the development of reagents, including antibodies, antigens, nucleic acid probes, or receptors attached to inert substrates, and toward the development of sensor systems with the capabilities to detect minute amounts of sample. The reagents, methodologies, and procedures are developed with the goal of detecting potential biological threat materials in clinical specimens as well as in-field specimens. The development of rapid diagnosis and detection prototype methodologies and equipment only requires the use of non-infectious materials, for example, antigens (proteins) purified from an organism, or other purified biological materials such as receptors, because the methodologies used do not depend on the growth of an organism. During the development phase, toxoids (inactivated and detoxified toxins) are used to test methods, procedures, and sensitivity of detection systems. All of the work conducted in support of this program effort is safely conducted in BL-l or BL-2 facilities.

5.3 Rationale for BDRP Rapid Diagnosis and Detection Efforts

A good defensive posture against potential biological warfare threats includes the development of methods to detect such threats in a field setting, as well as the development of diagnostic systems that could be used to determine, in a timely manner, whether such an attack has occurred. In the case of biological threats that could cause severe disease or toxicosis, the ability to detect or diagnose the threat agent in a timely manner could potentially be a significant consideration to the personnel at risk.

5.4 Environmental, Health and Safety Considerations

Because the development efforts described here do not involve the use of either toxic or infectious materials per se, laboratory workers involved in the rapid diagnosis and detection programs are exposed to little risk beyond that associated with the ordinary commercial or industrial workforce. There are no significant or minor environmental or safety considerations associated with these development efforts.

5.5 Waste Materials

The non-infectious, non-toxic waste materials generated in laboratories involved in rapid diagnosis and detection are disposed of in accordance with routine, accepted procedures for the disposal of general laboratory wastes. Any potentially infectious or toxic materials would be disposed of only after proper sterilization or decontamination as described for low or high hazard organisms, or toxins in the preceding sections.

5.6 Security

The access restrictions for BL-l and BL-2 laboratories are described in Appendix 12. Because the reagents and materials used in the development of rapid diagnosis and detection procedures and systems present only minimal risk to laboratory workers or to the environment, extraordinary security precautions are not warranted.

5.7 Accidents and Incidents

There have been no accidents or incidents among laboratory workers, their close associates, or the general community from the biological materials used specifically in the development of rapid diagnosis and detection systems.

5.8 Program Benefits

The development of rapid identification and diagnosis methodologies, and remote and laboratory detection equipment for potential biological warfare threat agents enhances the national defense posture with respect to these threats. The results of the BDRP efforts in rapid diagnosis are of benefit to the general population, as these efforts have resulted in the development of sensitive assays for the identification of various exotic, endemic diseases in clinical specimens. Scientists associated with this portion of the BDRP have, on numerous occasions, shared their expertise, methodologies, and reagents with health scientists in other countries where outbreaks of diseases such as Rift Valley fever have occurred. BDRP scientists provided diagnostic reagents and expertise to assist in the diagnosis and management of a recent outbreak, in U.S. troops stationed in the far East, of hemorrhagic fever with renal syndrome.

6. Vaccine and Drug Therapy Development

6.1 Introduction

This subject area is a major identifiable element of the BDRP in which the potential risks or impacts are of a markedly different nature than those evaluated under the other categories. This subject area includes only the preclinical and clinical testing of potential therapeutic compounds, i.e. antiviral drugs or anti-toxin drugs, immunomodulators, antibodies and vaccines. The other aspects of drug and vaccine development involving use of infectious organisms or toxins are covered under one or more of the other subject area risk/issue categories.

6.2 Types of Studies Conducted in Vaccine and Drug Therapy Development

Preclinical drug or vaccine testing, as the term "preclinical" implies, involves testing only in animals or with *in vitro* laboratory experimental systems. Any "challenge studies", where the efficacy of a drug or vaccine is tested against the disease or toxin of interest, are considered for the purposes of the IAM analysis under the appropriate risk/issue category, i.e. high hazard organisms, low hazard organisms, or toxins. Phase I clinical trials involve small numbers of human medical research volunteers; the object of a phase I clinical trial being to establish the safety of the drug or vaccine of interest and the appropriate dose ranges. Phase II clinical trials are conducted with relatively small numbers of human volunteer subjects (on the order of tens of individuals) to obtain initial estimates of efficacy by measuring immunogenicity. Phase III clinical trials are conducted in larger numbers of volunteers (on the order of hundreds to thousands) in order to establish statistically significant efficacy data. This phase of testing is not performed at the BDRP primary sites.

Phase III clinical testing of drugs or vaccines is only conducted where and when a target disease occurs naturally. Such human testing is conducted under appropriate controlled conditions meeting the human testing standards of the United States and of the country in which a study may be conducted. There is no introduction of an organism into the environment, and no additional risk to human or environmental health and safety over that which is a result of the occurrence of natural, endemic disease.

Representative vaccines in various stages of development in the BDRP include: the live, attenuated Chikungunya and Junin viral vaccines, an improved anthrax vaccine, an improved Q fever vaccine, and an improved Rift Valley fever vaccine. Efforts to improve the efficacy of existing vaccines or toxoids include developmental studies of microencapsulated vaccine and other immunogen delivery systems. The development effort for drugs effective against viral diseases has advanced to the point where one antiviral drug is in phase II clinical trials. The development effort for drugs effective against the various toxins of interest is still in its infancy, with the effort focused on basic and exploratory research.

6.3 Rationale for BDRP Vaccine and Drug Therapy Development

The goal of the drug development efforts conducted in the BDRP is to identify and develop, for human use, broad-spectrum therapeutic and prophylactic drugs and immunomodulators that would be effective against viruses and toxins. The pharmaceutical industry has, over the years, developed numerous antibiotics, and many of these are effective in treatment of the bacterial and rickettsial diseases studied in the BDRP. The development of antiviral and anti-toxin drugs is in its infancy in comparison to the status of antibiotic development. In addition, the pharmaceutical industry does not place a high priority on development of drugs for treatment of diseases that do not have a significant incidence of occurrence in the United States or other western countries. Thus, the drug discovery effort for the diseases and toxins of interest in the BDRP, which are primarily naturally occurring diseases found in other parts of the world, is undertaken within the BDRP.

Similar considerations pertain to vaccine development. The U.S. pharmaceutical industry is primarily interested in the development of vaccines for communicable diseases prevalent in the United States. The biomedical communities of many of the countries where the viral diseases *of* interest are endemic are in no position to undertake vaccine development efforts. Because the goal of the BDRP is to provide protection against potential biological warfare threats as well as against endemic diseases to which troops may be exposed, efforts to develop effective vaccines for selected viral diseases are an important part of the program.

6.4 Environmental, Health and Safety Considerations

There is always a finite element of risk involved in testing experimental drugs or vaccines in human volunteers. For this reason, such testing is closely regulated by the NIH the Food and Drug Administration, and within the DoD. There is no known significant risk to the environment arising from RDT&E activities conducted in support of vaccine and drug therapy development.

6.5 Waste Materials

The only waste materials that could be of concern in vaccine and drug development, other than materials covered in other risk/issue categories such as high and low hazard organisms, would be live, attentuated organism vaccines. Such materials are killed by autoclaving or by chemical inactivation before disposal. Syringes, needles, and other medical supplies that have had direct contact either with bodily fluids or biological materials are disposed of in accordance with standard procedures, i.e. in puncture-proof receptacles, closed waste containers, and autoclaved before disposal.

6.6 Security

Any drugs or vaccines used in studies designed to support an application to the FDA for exemption as an investigational new drug (IND) (or biologic product) are closely controlled, monitored, and accounted for. Access to these materials is limited solely to authorized investigators, and all use of the test materials must be documented thoroughly. An additional security consideration unrelated to environmental issues is that patient medical records and medical records from clinical trials are subject to the provisions of the Privacy Act.

6.7 Accidents and Incidents

There have been no accidents or incidents among laboratory workers, their close associates, or the general community from the biological materials used specifically in vaccine and drug therapy development.

6.8 Program Benefits

The availability of useful drug therapies for treatment of diseases or toxicoses that could be caused by potential biological warfare threat agents would be a great benefit to the national defense posture. The public benefits of this effort are the potential discovery and/or development of vaccines and treatments for diseases and toxicoses that are significant public health problems in many less developed parts of the world.

7. Other Program Research and Development Activities

7.1 Introduction

This category includes those subject areas of the BDRP that do not appropriately fit into one or more of the categories defined previously, that are likely to have imperceptible, if any, program-unique impact on the human or natural environment, and were not discrete subject areas warranting separate consideration.

7.2 Types of Studies Conducted

Examples of the sorts of activities included in this category are literature studies, purification of antibodies from immune plasma or hybridoma cells, growth of cultured animal or insect cells for use in experimental studies, manipulation of mouse spleens and cultured non-human cell lines for the creation of hybridoma cell lines that secrete monoclonal antibodies, purification of proteins or enzymes after isolation from cultures of various organisms, and light and electron microscopy (Microscopy samples are chemically inactivated and embedded in wax or plastic resins). Also included in this category are activities involving the chemical synthesis of potential therapeutic compounds in support of the Vaccine and Drug Therapy Development program area. These efforts are conducted in organic or medicinal chemistry laboratories, and are not considered to be significant or program-unique in that the BDRP-related fraction of this effort on a national scale is infinitesimally small. In addition, the BDRP-supported chemical synthesis efforts are no different in nature from those supported by the pharmaceutical industry, and are many orders of magnitude smaller.

7.3 Rationale for other BDRP Research and Development Activities

Most, if not all, of the activities identified above can be viewed as "support" efforts for the other program areas of the BDRP. As such, they are integral components of the program but do not play a discrete role in defining the BDRP.

7.4 Environmental, Health and Safety Considerations

With the exception of specific considerations for certain laboratory chemicals and reagents employed in these "other activities," there are no BDRP-specific environmental, health or safety considerations that differ in any way from the general considerations for these areas that apply in the public, commercial arena. Certain chemicals used in biomedical studies are classified as explosive, oxidants, flammable, toxic, irritant, corrosive, or biohazardous. The quantities of such materials used within the BDRP are extremely small, on the order of milligrams or grams, or liters, per year. These quantities are on the order of millions of times smaller than those employed in the chemical and pharmaceutical industries, and therefore represent a proportionally miniscule hazard. None of the chemicals used within the BDRP is classified as Surety Materials and therefore do not require coverage by DA chemical surety regulations.

7.5 Waste Materials

Laboratory materials that are non-toxic, uninfectious, and not biohazardous are appropriately disposed of in the ordinary waste stream. Chemicals or substances subject to coverage in the Resource Conservation and Recovery Act (RCRA) regulations (40 CFR 261.5(g) et seq.) are collected, identified, manifested, and disposed of by private contractors specifically licensed under applicable state programs to perform such disposal.

7.6 Security

The facility security provisions employed for the protection of real and personal property provide the appropriate level of security for the materials and activities identified in this program category. Specific storage requirements for volatile or explosive chemicals are mandated by OSHA and NFPA regulations and implemented through institutional safety offices.

7.7 Accidents and Incidents

By and large, the accidents or incidents related to this category of activities are the same sorts as one would encounter in everyday life, for example, getting a cut from broken glass. As described above, the quantities of potentially hazardous chemicals used within the BDRP are so small that only extremely localized effects could arise from any accident or incident. The only possible hazard would be to the laboratory worker.

7.8 Program Benefits

In that the activities described here support other BDRP functions, they contribute to the overall benefits of the BDRP in the areas of national defense posture, contributions to the scientific community, and to public health.

References Cited in Appendix 4

1. "Biosafety in microbiological and biomedical laboratories," J. Richardson and W. Barkley, eds. (1984) U.S. Dept. Health & Human Services Publication no. (CDC) 84-8395, Washington, D.C.

2. International catalogue of arboviruses including certain other viruses of vertebrates, third ed., (1985), N. Karabatsos, ed., Am. J. Trop. Med. Hyg., San Antonio, TX.

3. Levitt, N. H., H. H. Ramsburg, S. E. Hasty, P. M. Repik, F. E. Cole, Jr., and H. W. Lupton. (1986) "Development of an attenuated strain of chikungunya virus for use in vaccine production." Vaccine 4:157-162.

4. "Pocket handbook of infectious agents and their treatments," N. L. Hartman D. M. and Shapiro, eds. (1987) Avery Publishing, Garden City Park, NY.

5. DHEW, National Institutes of Health, "Recombinant DNA research guidelines," Federal Register 41:27902-279143 (1976)

6. DHEW, National Institutes of Health, Guidelines for research involving recombinant DNA molecules," Federal Register 51:16958-16985 (1986).

7. FEIS on the NIH guidelines for research involving recombinant DNA molecules of June 23, 1976, DHEW Publication No. (NIH) 1490, Bethesda, MD. (1977).

8. Environmental assessment of NIH guideline revisions, Federal Register 43:33096 (1973).

9. "Biological and toxin weapons today," E. Geissler, ed. (1986), Oxford University Press, NY.

APPENDIX C
DOCUMENTATION OF THE QUALITY OF THE ASH FROM THE PATHOLOGICAL WASTE INCINERATOR

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL RESOURCES
1875 New Hope Street
Norristown, PA 19401
215 270-1948

December 15, 1988

Joseph A. Grosskettler
Grand Central Sanitary Landfill, Inc.
1963 Pen Argyl Road
Pen Argyl, PA 18072

Re: Form 35 Submission
The Salk Institute
Autoclaved and Incinerated
Biological Laboratory Waste

Dear Mr. Grosskettler:

Your Form 35 submission for the disposal of autoclaved and incinerated biological laboratory waste from The Salk Institute has reviewed by our Regional Chemist Calvin E. Ligons

It is our conclusion that this waste is acceptable for disposal at your landfill site. Therefore, approval is granted for you to accept 36 tens annually of autoclaved and incinerated biological laboratory waste from The Salk Institute at your landfill site.

This approval has teem granted based on microbiological test data obtained utilizing the Incinerator Biological Destruction Efficacy procedure Future microbiological testing must be done using the procedure outlined by the Department via sterility testing.

Very truly yours

RUTH M. PLANT
Waste Management Facilities Specialist

cc: Mr. French
Mr. Maiolie
Re 30 (DCN1)349.13

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APPENDIX D
ESTIMATED CONCENTRATION OF FORMALDEHYDE EXHAUSTED FOLLOWING DECONTAMINATION PROCEDURES

Estimated Concentration of Formaldehyde Exhausted
Following Decontamination Procedures

A. Volume of laboratory room
= 4000 cubic feet

B. Concentration as ppm
= 3 mg paraformaldehyde/ft^3
= 10.8 ppm

C. Exhaust rate
= 4000 ft^3 x 10 air exchanges/hour/60 minutes/hour
= 667 ft^3/minute

D. Dilution factor

1 *Worst Case Scenario*
Cloud dispersion areas assume no loss of paraformaldehyde and no wind.
a) Roof Level
12 ft^2 stack opening /2048 ft^2 cloud dispersion area
= 1:170
= 0.06 ppm

b) Ground Level
12 ft^2 stack opening /5000 ft^2 cloud dispersion area
= 1:417
= 0.025 ppm

2. *Expected Scenario*
a) Formaldehyde reaches equilibrium at 3 ppm.
b) Exhaust is dispersed by wind.
c) Dilution is increased proportionate to wind speed example: 5 mph wind = 440 ft dispersion/minute if cloud dispersion remains unchanged. Ground Level: 12 ft^2 stack opening/22,000 ft^2 cloud dispersion = 1:1833 Original 3 ppm is diluted to 0.0016 ppm.
d) Actual dilution is much greater as cloud would break-up as it escaped the building envelope.

mg=milligram; ppm=parts per million; ft^3=cubic feet; ft^2=square feet

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APPENDIX E
NUCLEAR REGULATORY COMMISSION LICENSE HELD BY TSI-GSD

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. The Salk Institute Government Services Division	3. License number 37-28692-01
2. P.O. Box 250 Swiftwater, Pennsylvania 18370	4. Expiration date March 31, 1997
	5. Docket or Reference No 030-32502

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Any	A. 120 millicuries
B. Carbon 14	B. Any	B. 10 millicuries
C. Phosphorus 32	C. Any	C. 10 millicuries
D. Sulfur 35	D. Any	D. 25 millicuries
E. Iodine 125	E. Any	E. 1 millicurie
F. Iodine 131	F. Any	F. 1 millicurie

9. Authorized use

A. through D. Research and development as defined in Section 30.4 of 10 CFR Part 30.
E. through F. *In vitro* laboratory studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at The Salk Institute, Government Services Division, P.O. Box 250, Swiftwater, Pennsylvania.

11. A. Licensed material shall be used by, or under the supervision of, Noah J. Burns, Ph.D., Firelli Alonso-Caplen, Ph.D., and Michael P. Kiley, Ph.D.

    B. The Radiation Safety Officer for this license is Michael P. Kiley, Ph.D.

12. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days and Sulfur 35 for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

NRC Form 374A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 OF 2 PAGES

License number
37-28692-01

Docket or Reference number
030-32502

MATERIALS LICENSE
SUPPLEMENTARY SHEET

(Continued)

CONDITIONS

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated August 22, 1991
    B. Letter dated January 31, 1992
    C. Letter dated February 21, 1992

For the U.S. Nuclear Regulatory Commission

Date MAR 0 6 1992

By Original Signed By: John D. [illegible]

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

APPENDIX F
PROGRAMMATIC ALTERNATIVES CONSIDERED
TAKEN FROM THE BDRP FPEIS, SECTIONS 4.1 - 4.5

4. ALTERNATIVES CONSIDERED

4.1 INTRODUCTION

The treatment of alternatives is the heart of the EIS. For every choice among alternatives, there are trade-offs which must be considered A goal of the alternatives presentation is to define clearly the issues to provide a basis for choice among options by the decision maker and the public (40CFR1502.14).

Two alternatives are readily identified:

a. Continue the *BDRP* (essentially as presently constituted)
- This is considered to be the Preferred Alternative.

b. Terminate the BDRP - This is designated as the "No Action" alternative.

It is important to note that termination of the BDRP has been designated as the "No Action" alternative, and that this is contrary to the manner in which "no action" may normally be interpreted. Maintenance of the status quo [unaltered environment) is usually inherent in the no action alternative. This would not be the case, however, because the BDRP is an ongoing program. Termination would definitely alter the status quo. This will be discussed further as the reasonable alternatives are compared.

Other possible alternatives relate primarily to different ways of conducting the BDRP or to selection of different locations for conducting research or testing activities. These options are grouped as "changes in the scope" or "changes in the location" of the program.

The primary reason for considering alternatives, in accordance with NEPA, is to provide reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions on the quality of the human environment.

The degree to which the BDRP could affect the quality of the human environment is subject to debate or differences of opinion. The IAM process, utilized to assist in focusing on the truly relevant and significant issues, revealed that the perceived risks and associated impacts were, in many instances, quite different from the actual risks and the observed or realistically expected impacts (See Appendix 6).

4.2 ANALYSIS OF ALTERNATIVES

In addition to the two most obvious alternatives identified above, considerable effort was devoted to searching for other reasonable alternatives. The IAM assisted in the identification of relevant and significant areas of concern. This approach also provided a mechanism to identify any potential significant impacts and the resources that could be affected. The BDRP was systematically examined both on a programmatic and on a site-specific basis. The IAM process led to the following conclusions for the ongoing BDRP (Preferred Alternative):

a. Negative or adverse considerations

(1) Public opinion, as manifested in the controversy surrounding the BDRP or portions of its content (such as genetic engineering), was identified as a relevant concern or issue. (Details on the controversial issues are presented in Section 5.2 and Appendix 10.) -

(2) Impacts, perceived by elements of the public, on the following resources:

(a) Water quality

(b) Air quality

(c) Human health

(These perceptions are apparently based primarily upon distrust, lack of accurate information, or misunderstandings related to the adequacy of control measures and/or the nature of physical containment facilities.)

b. Positive or beneficial considerations

Contributions to the national defense posture and scientific benefits (See Section 1.5 for details).

The following conclusions are based on the consideration of alternatives and the identification of relevant and significant
issues (See Appendix 6):

(1) All significant issues relate to the BDRP, and not to specific sites.

(2) The impacts of the BDRP fall into the category of perceived impacts; no actual significant-adverse impacts were identified.

(3) No conflicts of resource use were identified.

4.2.1. ALTERNATIVES RECOMMENDED BY SCOPING

The Notice of Intent to prepare this EIS identified the proposed action as the continuation of the BDRP and solicited alternatives to be considered from other agencies and the interested public. In addition to suggestions that the BDRP be terminated (No Action alternative), the following alternatives [paraphrased) were suggested: *

a. Use innocuous agents or simulants in lieu of hazardous biological organisms for research or testing.

b. Environmental considerations should guide selection of location of research or testing sites.

c. Options to replace aerosol testing should be considered.

d. Place a moratorium on research involving genetic engineering.

e. Transfer the management of the BDRP to a non-military agency.

The first four suggestions represent modifications in the program scope, or potentially changes in locations, while the last would alter the present management authority. Each of these recommended alternatives was analyzed both in the NEPA context, and in the context of its possible effect on the BDRP for its potential to alter conflicts in the use of available resources or to change (especially reduce) any significant impacts on the human environment. As discussed below, none of these alternatives, if implemented, would result in any significant changes in utilization of resources or in amelioration of any adverse impacts on the environment. Thus, these alternatives were eliminated from more detailed study and from further consideration in the identification of reasonable alternatives.

4.2.2 ANALYSIS OF SCOPING AND PUBLIC COMMENT RECOMMENDATIONS

a. Use innocuous agents or simulants in lieu of hazardous biological organisms for research or testing.

Maximum use of simulants is already part of the BDRP It is standard practice to use lower hazard organisms or simulants, to the extent practicable, in the conduct of research and testing. Research design considers the objectives to be sought and seeks

* It should be noted that each of these suggested alternatives was also identified in some fashion by various commentors in their comments on the DEIS (see Appendix 14).

to accomplish these objectives in a manner which is both safe and cost effective. If lower hazard organisms, or simulants, will meet the objectives, they are normally selected. Even so, the higher hazard organisms must be used for certain efforts, for example, in evaluating the efficacy of a vaccine or drug, and in the development of a diagnostic assay or of a detector. Vaccines or drugs must provide protection or therapy against a particular disease and must be tested in animal challenge studies against that disease to demonstrate their effectiveness. In the case of diagnostic assays, many experimental concepts can be and are developed using lower hazard organisms, but ultimately actual pathogens must be used in the laboratory in order to assure sensitivity and reliability. Similarly, in the development of detection systems, the detection paradigm can be developed using lower hazard organisms, but that paradigm then needs to be tested in the laboratory using higher hazard organisms in order to ensure sensitivity and reliability, especially in cases where a component of the detection system is based on a biochemical property unique to a specific organism. In the case of detection or protection systems based solely on a physical parameter, such as particle size, only simulants or lower hazard organisms are needed and therefore are used for those RDT&E efforts. In all cases, when the more hazardous materials must be used, test protocols are designed to use only small quantities of infectious organisms or toxins, and to incorporate appropriate procedures and containment to protect adequately the workforce and external environment. The IAM did not reveal significant adverse impacts to the environment nor conflicts in the use of resources arising from the use of higher hazard organisms in the BDRP. Thus, the alternative of increased or exclusive use of simulants in the program was not considered a viable alternative in the NEPA context.

b. Environmental considerations should guide selection of location of research or testing sites.

In regard to this second alternative recommended in scoping, environmental considerations can and do influence the location of some BDRP activities. Obviously, if there are no potential adverse environmental consequences which would differ from site to site, then the location is not a relevant area of consideration. Most of the potential impacts associated with BDRP activities have been determined to be site independent. There are circumstances, however, such as the selection of the remote DPG area for any open-air field tests with simulants which may be required, which are definitely dependent upon considerations of location (See Appendix 5). In addition, if potential accidents resulting from BDRP activities had been determined to threaten human or animal populations, then areas of sparse human population and poor habitat quality would need to be evaluated. This-is not the case because no such threats are identified (See Appendix 9).

c. Options to replace aerosol testing should be considered.

The recommendation to eliminate aerosol testing would seem to provide an opportunity to reduce a few of the dangers or risks associated with BDRP activities. Transmission of infection through aerosols does represent one of the greatest risks to laboratory workers. However, most laboratory infections that have occurred in the past have been attributed to accidental or incidental aerosol release from other laboratory procedures and have not been associated with aerosol testing per se (5) and see Appendix 8). In addition, airborne particles (aerosols) are considered the most likely manner in which a biological attack would be initiated. Therefore, the design and testing of defensive materiel, such as protective devices and detectors, must address this factor. This preeminent consideration, together with the fact that a vaccine that is effective against disease transmitted by inoculation might not be effective against the same disease when transmitted by aerosol challenge (83), makes aerosol testing a necessary element of the BDRP Studies requiring the use of aerosols are, like any other studies, designed to answer a specific scientific question, and thus are conducted only infrequently and only in the larger context of the goals of a particular project. Aerosol testing with all organisms (except those officially designated as simulants) is conducted only on very small scale, in sealed chambers, in biocontainment laboratories. Aerosol testing conducted in the BDRP is not large scale, and the potential risks associated with aerosol testing are mitigated by the use of special procedures, specially designed equipment, and appropriate levels of containment, which effectively reduce the risks and protect the work force and the external environment. Because the risk to health and the environment are minimal, after consideration of mitigative measures, and because elimination of aerosol testing would make the BDRP ineffective, this alternative is not considered to be reasonable.

d. Place a moratorium on research involving genetic engineering.

Genetic engineering adds a significant research tool to the scientists' repertoire. It is a widely accepted scientific approach, albeit an area of concern to certain elements of the public. Genetic engineering, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind. The scientific community is well aware of the possibilities for harmful effects and has responded by establishing stringent guidelines to minimize any impacts of genetic engineering on the human environment (See Appendix 10).

A moratorium on the use of genetic engineering as a research tool would probably alleviate at least a portion of the opposition to the BDRP and might well also reduce some of the controversy. It would also eliminate some of the concerns for postulated catastrophic events, especially for those who envision the uncontrolled spread of a novel hazardous organism. However, because the BDRP does not include any efforts whatsoever to produce novel hazardous organisms, this concern seems unrealistic. The elimination of genetic engineering would render a substantial portion of the BDRP scientifically ineffective and reduce the overall level of defensive “preparedness." Therefore, this recommended alternative is not considered to be reasonable.

e. Transfer the management of the BDRP to a non-military agency.

For those distrustful of the military, the fifth suggested alternative of transferring program management responsibilities to a non-military agency, for example the NIH would appear to be an attractive option. It is also conceivable that another Federal agency, or perhaps a specially appointed board, could direct the BDRP Such an approach might alleviate the criticisms of the military management of the BDRP but it would not necessarily lessen the controversies or concerns related to such issues as genetic engineering, high hazardous infectious organisms, or aerosol testing. It is assumed that these issues would remain areas of concern because they are vital to the BDRP, regardless of the management authority. If BDRP type RDT&E efforts continued, it does not necessarily follow that there would be any reduced risks to the work force or the general populace. Different or additional management also would not necessarily improve the existing, excellent safety record of the BDRP. Thus, the transfer of management would not affect utilization of resources or environmental impacts.

A pertinent consideration to the "change management" alternative is that the BDRP is a vital component of the national defense posture. While certain scientific, programmatic, or research management responsibilities could possibly be transferred from the military, this is not the case for defense responsibilities. The DoD is responsible for recommending to the Congress adequate measures to defend the U.S. and its allies successfully. It would not be appropriate, even if it could be done institutionally, to transfer defense responsibility to another agency or organization.

In any event, it is not clear what would be gained from a transfer of management. Presumably, it might alleviate some of the fears of those who distrust the military. However, as for the BDRP there are no clandestine objectives. The BDRP is an open UNCLASSIFIED program, however, results which impinge on National Security may be classified as described in Section 2.1. As discussed in Section 5.5, the participation of postdoctoral fellows from other nations is one example of this openness. In addition, independent scientists already review RDT&E activities and provide guidance on various aspects of the program, and a substantial portion of the research is conducted in non-military establishments (See Appendix 3). Finally, the U.S. Congress is provided a report on the BDRP annually. This report, which is available for public scrutiny, informs the Congress of the objectives of ongoing and future BDRP efforts, accomplishments to date, and identified future needs. Certain aspects of the BDRP especially safety, have also been evaluated by such external entities as the Government Accounting Office and a Congressional subcommittee (84, 35). With an appreciation of the openness of the program and the existing external oversight, along with an understanding of the need for military Involvement, the benefits that would accrue to the nation, or the human environment, from a transfer of management are not apparent. In addition, it is anticipated that the efficiency of the program would decrease with the addition of another level of management, without any indication that new management would be better, or that the BDRP would be executed more cost-effectively or responsibly. Therefore, the option of transferring program management from the DoD to a non -DoD agency was rejected as not being a reasonable alternative.

4.3 COMPARISON OF REASONABLE ALTERNATIVES

The approach used in identifying the relevant and significant areas of concern has assisted in sharply defining the issues and in providing a clear basis for choice among alternatives. Based upon the preceding discussion, the alternatives have been narrowed to two, i.e. the preferred alternative (Continue the BDRP) and the no action alternative (Terminate the BDRP). Other possible alternatives were eliminated from consideration because they:

(1) Are already an integral part of the BDRP, and are thus fully incorporated in the preferred alternative.

(2) Would render the program ineffective.

(3) Would not materially improve the program, resolve conflicts in resource utilization or reduce impacts.

Early in the scoping process, it appeared that modification of the program scope, content, or location might be reasonable alternatives. Because no substantive approaches to improving or protecting the human environment were identified, these alternatives were also eliminated from further detailed study. This conclusion and the resultant narrowing of the issues should not be viewed as representing a complacent attitude. The ongoing BDRP has areas which can be improved and efforts are continually being made in this regard. For example, safety and security measures are the subject of intense oversight. Appropriate adjustments are implemented as needs or opportunities to upgrade or improve are recognized. Some changes have been incorporated and still others are proposed (see Section 3.3.2). While greater levels of safety may accrue, such adjustments in and of themselves do not constitute alternatives, nor do they materially affect any existing impacts arising from the BDRP.

Considerable sensitivity is also exhibited in managing GEM - activities in the BDRP. An active Institutional Biosafety Committee, which includes lay representatives from the local community, reviews all research protocols involving GEMs to assure that studies-of recombinant DNA or genetically engineered organisms comply fully with the recommendations of the NIH guidelines. If there is any question as to the risk or propriety of a proposed study, external review and approval are sought through the NIH/RAC process, as specified by the NIH guidelines.

The concern for, and attention paid to, the safety, health, and welfare of the work force, as well as for protection of the external environment, are illustrative of the commitment on the part of the proponent to manage the BDRP responsibly. Thus, it was not considered necessary, nor appropriate, to develop a subset of alternatives which would merely reflect differing levels of emphasis or special attention to selected elements of the overall program.

Table 2 provides an overview of the significant issues, impacts, and tradeoffs associated with the two reasonable alternatives. The tradeoffs are basically between the amount or intensity of controversy and program benefits. The actual adverse impacts to the biophysical and socioeconomic environments associated with the BDRP are not significant and therefore cannot represent an area of consequential gain or loss. Termination of the BDRP would adversely affect individuals in the work force and would have an adverse effect on the local economy in the areas where BDRP efforts ceased. The greatest impact would occur to Frederick County, MD, where BDRP activities support about 3.5 percent of the county's total payroll. This would be within the range of economic impacts experienced over the past 12 years in the area, but would be considered locally significant. Other locales would be adversely affected to a much lesser extent depending upon the location and amount of funding involved.

It is clear that designating termination of the BDRP the "no action" alternative is a misnomer. The status quo would change as indicated in Table 2. It is also clear that any gains or positive contributions to the human environment associated with terminating the program are speculative, as opposed to tangible losses that would result from termination.

4.4 FUTURE CHANGES IN SCOPE, CONTENT OR LOCATION

No specific major changes in scope, content, or location are currently proposed, nor have any requirements (or advantages) for change been identified during the preparation of the FEIS. Relatively minor adjustments or refinements, within the context of the overall BDRP, are made on a routine basis. The review and approval of a new research proposal serves as an example. This could result in a change in program content and/or location. Each activity of this type is provided appropriate NEPA analysis and documentation, depending upon the circumstances and the

TABLE 2
COMPARISON OF REASONABLE ALTERNATIVES

ALTERNATIVE	IMPACTS/ISSUES	REMARKS
Continue BDRP (See Section 2 and 3 for Description). This is the Preferred Alternative.	1. The program evokes controversy among segments of the public which will continue along with the concerns and apprehensions.	1. This is an issue and not an impact *per se*. The appropriateness of BD research, along with the use of high hazard infectious organisms and genetic engineerng in the program, represent primary areas of concern.
	2. Perceived adverse impacts related to: a. Water Quality b. Air Quality c. Adequacy of physical containment facilities. d. Health of the workforce.	2. The actual adverse impacts for these categories were determined not significant for either normal operations (with controls in place), or for accident/incident situations. All ongoing activities are in compliance with appropriate regulatory provisions (See Sections 5 and 6).
	3. Program benefits: a. National defense b. Scientific c. Public health benefit	3. It is the position of DoD that the defense against potential BW represents a vital component of the overall defense posture. Positive defense contributions accrue. This is an issue, not an impact. Tangible benefits accrue to the scientific and medical community (See Section 1.5). The BDRP does have an indirect positive benefit on human health.
Terminate BDRP (This means that funding would be eliminated and all RDT&E activities halted.) This is the "No Action" Alternative.	1. The controversy and concerns related to BD research and development would be eliminated.	1. Because BD research is only a very small part of the overall research and development involving genetic engineering, controversy on this issue would continue. Research involving toxins and infectious organisms would continue in other non-military programs.
	2. Perceived impacts and risks would be eliminated.	2. No measurable improvement to the human environment would be realized since the significant adverse effects were perceived rather than actual.
	3. Contributions to national defense and to the scientific community would be forfeited.	3. Greater vulnerability to enemy attack would exist. The rapid response capability to emergency situations would not be available and the contributions to basic science and health measures would not accrue.

potential for impacts. The tiering approach developed in this programmatic FEIS, based on programmatic risk/issue categories, provides a framework for future environmental review and documentation. Any proposed major change in the scope of the BDRP will be examined based on its own set of circumstances, including any site specific considerations which might exist. Likewise, a proposal for development/construction of new or expanded facilities would be expected to involve site specific considerations as well as programmatic issues. The general goals of resource conservation and environmental protection will certainly influence future proposals and actions. Assurance of appropriate environmental compliance will be an integral component of the review process for all future activities.

APPENDIX G
AFFECTED ENVIRONMENT
TAKEN FROM THE BDRP FPEIS SECTION 5.1 - 53

5. AFFECTED ENVIRONMENT

5.1. INTRODUCTION

The BDRP is an ongoing research program conducted in existing facilities. Therefore, the day-to-day conduct of the program activities does not require further alteration of either the biophysical or socioeconomic environment. Construction activities associated with the program have occurred on an infrequent basis, and if further needs arise, the proposed actions will be subjected to individual site specific evaluations, with appropriate NEPA documentation in accordance with 40 CFR 1500-1508 and AR 200-2. Air and water effluents and solid wastes emanating from the BDRP are subject to Federal, state, and local controls designed to protect against adverse impacts. Where appropriate, liquid waste streams from BDRP research facilities are pretreated (see Section 5.3) then discharged into established treatment facilities for final treatment before release to the environment.

This section of the DEIS provides a general description of only those aspects of the biophysical and socioeconomic environments that potentially could be affected by the BDRP. The environments described in this section correspond to the set of "Potential Areas Impacted" as displayed on each Impact Analysis Matrix (IAM) in the BDRP evaluations, displayed in full in Appendix 6. Through this evaluation process, decisions were made as to which aspects of any environment were relevant for consideration in the body of this EIS. Appendix 5 contains a fuller description of the environment, whether or not considered to be potentially affected, of the primary sites and of selected secondary sites.

Existing environments associated with specific research sites, and which were shown by the IAM to have some potential to be affected in a particular location, are described in section 5.3. The CEQ regulations (40 CFR 1502.15) require that the presentation of these descriptions be sufficient to understand potential effects, and the data and analyses be commensurate with the importance of the impact. Less important material that requires inclusion in this presentation is summarized, consolidated or referenced. Because analyses performed for this study determined that the potential for effects was very small in many cases, treatment of those aspects of the environment is suitably brief. Considerable use is made of existing NEPA documentation (Environmental Assessments and EIS's) prepared for other purposes by the primary sites of BDRP execution.

5.1.1. Biophysical environment

5.1.1.1. Land Use. The general patterns of existing land uses on and surrounding the BDRP primary or secondary sites are evaluated in the following categories: agricultural, industrial, commercial. residential, recreational, wetlands, floodplains, and unique geographical areas. Relevant land use plans, policies, and controls, which could be affected by the BDRP activities are also considered.

5.1.1.2. Plant and Animal Ecology. The naturally occurring habitats surrounding the site are evaluated. Terrestrial and aquatic habitats, plant and animal populations, endangered or threatened species, and any designated critical habitats are the categories evaluated.

5.1.1.3. Geology. The land formations, soils, topography, and erosion characteristics of the soils in the area adjacent to the site are evaluated.

5.1.1.4. Water. Surface and ground water quality and quantity are evaluated in the area surrounding the site. Water use and supply are also evaluated.

5.1.1.5. Air Quality. Air quality of the area surrounding the site is evaluated. This includes a consideration of primary and secondary National Ambient Air Quality Standards and emission standards for "hazardous" air pollutants adopted under the Clean Air Act. The evaluation also includes consideration of appropriate biological and other parameters for which there are no standards.

5.1.1.6. Agriculture. Agricultural activities involving crops and livestock in the area surrounding the site are examined.

5.1.1.7. Cultural Resources. The existing districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places as well as other significant scientific, cultural, or historical resources are considered. The evaluation also includes the material remains of past human life and activities such as fossils, relics, artifacts, and monuments.

5.1.1.8. Energy Resources. The evaluation of energy resources includes depletable supplies such as oil, gas, and coal as well as renewable resources such as solar, wind, and water.

5.1.2. Socioeconomic Environment

5.1.2.1. Sociological Environment. The sociological environment of the area surrounding the site is characterized by its demographics, aesthetics, noise levels and odors.

5.1.2.2. Economic Environment. The economic environment in the area surrounding the site is characterized by the size of the labor force, personal income, business volume, and property values.

5.1.2.3. Public Opinion. Public opinion includes controversial issues such as laboratory animal care and use, infectious organisms, biotechnology, and existence of the BDRP in general. It also includes concerns such as socioeconomic well-being and other philosophical issues. Public opinion encompasses philosophical opposition to biotechnology in general, and the utilization of biotechnology in DoD-sponsored programs.

5.1.2.4. Program Benefits. The program benefits include the promotion of the existing posture of the United States with respect to defense against biological warfare threats. Potential general scientific and medical benefits include better methods of detection, treatment and prevention of various diseases, as well as increased understanding of basic biological and disease processes. It includes benefits to the public arising from the development of vaccines and drugs for naturally occurring animal and human diseases.

5.1.2.5. Transportation. The existing road, rail and air transportation systems are evaluated in the area surrounding the site. The existing traffic conditions on the roadways are also evaluated.

5.1.2.6. Human Health. Human health is considered for two distinct groups. The workforce at the site is evaluated as one group, since it is potentially at higher risk, especially the laboratory workers and medical research volunteer subjects. The other group is the general population of the area surrounding the site.

5.1.2.7. Safety. Safety considerations are evaluated at the site. This evaluation includes construction and occupational safety (OSHA activities) as well as consideration of past accident records.

5.2 NATIONAL ENVIRONMENT

The environmental impact analysis of the BDRP required an examination of all aspects of the program at the primary and secondary sites. Because several of the relevant areas of significant concern with the BDRP surfaced only from considerations of the total program, with little or no relationship to the sites of performance, the category "National Environment" was established to allow a meaningful discussion of these effects.

Appendix 6 lists all sites participating in the BDRP. Some of these locations are outside the United States. For a major action with the potential for effects outside the U.S., Executive Order 12114 (3CFR 356 (1980), as implemented by DoD Directive 6050.7 and AR 200-2, requires an examination of the potential to "significantly harm" the environment of another country. Although NEPA does not apply directly to BDRP sites outside the United States (as defined in AR 200-2), these sites were examined for any potential harm under E.O. 12114. No potential was found to significantly harm any aspect of the environment of any other country, and no further examination of international participants in the BDRP as distinct from other secondary sites, was conducted.

5.2.1 Relevant Areas of Significant Concern

Matrix analysis of the total BDRP revealed ten relevant areas of potentially significant concern which were not always intrinsically related to any one site. Seven areas of concern were associated with the biophysical or socioeconomic environment and three with program activities (see Appendix 6). The environmental areas potentially impacted are surface water, biological air quality, public opinion concerning controversial issues, program benefits with respect to the national-defense posture, scientific benefit and public benefit, human health with respect to the workforce, and safety during construction. The program activity areas identified as most likely to be responsible for potential environmental impacts were program management, planning and designing the research, development and testing program, and the performance of procedures required for this research, development, and testing. Program activities are defined in Appendix 6.

5.2.1.1 Surface Water

The potential risk to surface water quality is perceived to be high by some special interest groups and individuals, but actually is low when one examines the stringency of the controls that are applied to the effluents entering wastewater streams from all sites performing BDRP activities (See section 3.3 and Appendix 6). The potential for effects on surface water quality caused by site-specific BDRP activities is discussed in sections 5.2.2 and 5.2.3, below.

5.2.1.2 Biological Air Quality

The potential risk to air quality as a result of possible release of biological toxins or infectious organisms during BDRP activities is perceived to be high by some members of the public, but actually is low or virtually non-existent when one examines the stringency of the controls that are applied to the exhaust air leaving the BDRP facilities. See section 3.3 and Appendices 6, 9 and 12 for a discussion of the many safety controls in place which serve to minimize any potential for release of hazardous materials into the air. The potential for effects on biological air quality caused by site-specific BDRP activities is discussed in sections 5.2.2 and 5.2.3, below.

5.2.1.3 Public Opinion

Controversial Issues

The operation of the BDRP for the study of hazardous biological organisms and toxins brings with it the potential for controversy (40-71). The development of defensive measures for neutralizing the current threat of biological weapon and toxin employment against U.S. soldiers or allies requires the use of the most modern scientific research techniques. Of all the biotechnology available today, perhaps the most controversial (see Appendix 10) is the use of recombinant DNA (rDNA) molecules (41,42) in the construction of genetically engineered microorganisms (GEMs). The facilities supporting the BDRP include microbiological laboratories with modern technological design and equipment. Basic (BL-1 and BL-2) and high-hazard (BL- and BL-4 containment capabilities supported by the BDRP represent the latest in functional concepts, laboratory design, and safety (see Appendices 11 and 12). Safety features built into these laboratories permit studies of pathogenic, disease-causing organisms with minimal risk to research investigators and virtually no risk for the surrounding community.

Worldwide, USAMRIID is the one state-of-the-art containment facility which existed at the beginning of the genetic engineering era. USAMRIID's high-hazard containment laboratories are the model for the development of the physical containment recommendations in the first NIH Recombinant DNA Research Guidelines (34) and in its supplement, the NIH Safety Monograph (33). No member of the general public in any community has ever become infected with any natural or recombinant biological material as a result of research or test activities in the BDRP (Appendix a) . Since 1976, no BDRP laboratory worker has ever developed a disease as a result of infection with organisms studied in the BDRP laboratories. No resident of the surrounding community has ever developed a disease as a result of these research activities. Any allegation that the BDRP represents an actual community hazard at any location cannot be substantiated.

The BDRP currently includes research on high hazard microorganisms, GEMs, and biological molecules, including both high and low molecular weight toxins. The high molecular weight, or protein, toxins of interest include botulinum toxin, the staphylococcal enterotoxins, and several snake neurotoxins. The low molecular weight toxins include the trichothecene mycotoxins, algal toxins, marine, and various small, non -protein toxins such as saxitoxin and tetrodotoxins. All of these research and development activities are governed by the provisions of the Biological Warfare Convention "Appendix 1) and research results are routinely published in the open scientific literature. It may not ever be possible to eliminate totally some degree of public apprehension about a technically complex subject, such as research with infectious organisms, recombinant organisms, and toxins. However, BDRP research activities with these materials is comparable, in terms of risks, organisms, and quantities of materials used, to scores of ongoing university and health department -sponsored biological and medical research programs in the U.S. and other countries.

5.2.1.4 Program Benefits

National Defense Posture

A positive impact from the research activities of the BDRP is the contribution these efforts have on the national defense posture of the United States. For a time after the signing of the 1972 Biological and Toxin Weapons Convention, which prohibits the use of BW (See Appendix 1), there was only limited interest in BW defense research. However, there has been increasing evidence that the Soviet Onion and other countries have developed offensive BW capabilities. The nonverifiable nature of the 1972 BW treaty, and the realization that a realistic BW threat does exist, have renewed interest in defense against BW agents. Because BW is the only threat for which the U.S. possesses no capability for retaliation in kind, the existence of an active defensive research program serves as the only deterrent to potential adversaries in planning for indiscriminant use of bioweapons in operational war plans. The development of vaccines, prophylactic and therapeutic drugs, and diagnostic kits for biological agents and toxins, is believed to discourage our adversaries in their development of an effective, offensive, biological warfare arsenal

Scientific Benefit

Other positive impacts from the research activities of the BDRP are the contributions these efforts have had in the prevention and treatment of bacterial and viral diseases throughout the world. The conventional approach to medical defense against BW has been based on the development of prophylactic and therapeutic drugs, vaccines, and diagnostic kits for specific, naturally occurring toxins and infectious disease organisms. Potential threat agents were identified principally on criteria related to their ease of production by a hostile country or terrorist organization, physical and biological stability, and infectivity or toxicity when delivered as an aerosol. Protective products derived from the BDRP during the past several years include vaccines for anthrax, tularemia, Venezuelan equine encephalomyelitis (VEE), Rift Valley Fever (RVF), Q fever, and toxoids against five types of botulism. While many of these products are not yet licensed for general public use, they are used to protect at-risk laboratory workers and are shared with other at-risk populations under certain disease outbreak conditions. Thus, the scientific breakthroughs and product developments arising from the BDRP contribute to the scientific community with advances in basic knowledge and potentially to the health status of certain populations at risk from endemic diseases.

5.2.1.5 Human Health

Workforce

The potential risk to the health of the workforce is perceived to be high by some members of the public, but actually is low when one examines the stringency of the controls that govern each BDRP workplace {see section 3.3 and Appendices 6 and 9). An examination of the potential for effects on the workforce is included in the examination of each site where any such potential could be identified (see sections 5.2.2.3 and 5.3, below).

5.2.1.6 Safety

Construction

There are currently no new construction activities supported directly by the BDRP, thus, this EIS does not address any potential risks resulting from the construction or operation of new facilities. The potential risk to construction safety is perceived to be high by certain public interests but actually is low when one examines the stringency of the controls which are applied to construction operations supporting the BDRP. The basic issue apparently relates to concerns about the adequacy of the design, construction, and operation of the physical containment facilities (see section 3.3). Appendix 12 also describes the requirements for construction of any new containment laboratory. In addition, a separate assessment and NEPA documentation must be prepared by the proponent prior to any new construction by a U.S. government agency.

5.2.1.7 Program Management

BDRP management is conducted openly under Congressional review and in full view of the public in order to minimize program controversy and to maximize program benefit. Through a combination of intelligence information and biotechnological advancements from the scientific community, the commanders of the three primary sites, USAMRDC, USACRDEC, and USADPG, and their professional staff are responsible for recommending a scientifically sound, economically efficient, safe and responsible research program that adheres to BWC and contributes to the protection of soldiers and the defense of the Nation.

The management of the BDRP is a relevant issue from the standpoint of both positive benefits and negative perception. Enhancements of the national defense posture and contributions to scientific advancement are benefits from the program. On the other hand, certain public interest groups espouse the opposing view that any research in biological defense leads both to destabilization of international political relationships and to the potential for a return to offensive biological weapons capabilities which would nullify the BWC. This divergence of viewpoints and public perception establishes the controversy over the appropriateness of the BDRP.

5.2.1.8 Planning and Design

Planning and design differ from program management in that these are the activities in which BDRP scientists specifically develop test methods and design experiments. The actions are largely those of planning on paper and the development of procedural, health, and safety protocols on a project by project basis. It is at this stage that the course of the day to day laboratory work is determined, and appropriate safety precautions are included where necessary. Reference to appropriate safety standards and standard reference works is common. The health and safety protocols, animal use protocols, and human volunteer protocols are prepared at this stage and reviewed by the appropriate committees before any actual laboratory work is started.

5.2.1.9 Procedures

The relevant procedures are the sum of all the protocols, regulations, and requirements placed on the laboratory workers to regulate their day-to-day work. Essentially nothing is performed in a BDRP research laboratory without reference to project protocols or organizational standards. Procedures may be considered an important means whereby compliance with health and safety standards are assured.

5.2.2 Relevant Areas of Minor Concern

Matrix analysis of the total BDRP program revealed six relevant areas of minor concern, three associated with environmental areas and three with program activities (see Appendix 6). The potential areas affected include public opinion with respect to social concerns, program benefits in the area of public benefits, and the health of the general population. The program areas identified as most responsible for these potential impacts were testing, prototype development, and general laboratory work.

5.2.2.1 Public Opinion

Social Concerns

Four broad social concerns were examined. These concerns were: 1) That through genetic engineering, a deadly organism unknown to medicine or science could be produced and released 42-44,61,71); 2) That the research programs, especially at the primary sites, had the potential to involve many thousands of persons in a catastrophe caused by the release of an organism used in research (4a 54,61,69,71); 3) That few, if any, controls existed to regulate the type of research being performed at either the primary or the secondary sites; and 4) That biological warfare was so repugnant a concept that the U.S. should have nothing at all to do with consideration of even a defensive program with which to meet a potential threat (42, 43,59,69,70, 72). While these diverse feelings are grouped here under one heading, most have been discussed thoroughly as separate issues in other sections of this FEIS. We believe that each is closely related either to lack of accurate information about the BDRP or to strong personal convictions which are not likely to change even when the incorrectness of that misperception is strongly documented (72). Each will be examined briefly below.

Genetically Engineered Microorganisms -- Use of recombinant DNA procedures with pathogenic organisms and toxins is closely controlled at all locations, both within and outside the government. Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort In fact, BDRP uses of recombinant techniques are with the goal of-producing a less virulent strain which may be more safely used in the laboratory or for vaccine development. Section 3.3 and Appendix 10 discuss the many safeguards which preclude the development, let alone the release, of "deadly" recombinant organisms.

Catastrophic Accidents -- While a laboratory accident could potentially result In serious consequences to a member or members of the workforce (even one case of disease attributable to the BDRP would be considered serious), epidemic (i.e. a spread from person to person) resulting from organisms studied in the BDRP is technically and epidemiologically impossible. Appendices 7 and 9 describe some of the many reasons why major disease outbreaks are not a plausible consequence of the BDRP, even as a result of a laboratory accident. Appendix 9 discusses the most serious credible accidents. Appendix 8 describes the scope and magnitude of defensive biomedical research in perspective as compared to development of offensive biological weapons. Finally, it should be pointed out that while most of the organisms under study can cause human disease (otherwise they would not be considered a potential threat), most of the diseases studied are debilitating rather than deadly.

Controls on Research -- A discussion of the types of controls found to be in place at the primary and secondary sites Visited during this study (a part of Appendix 5) indicates that controls on the conduct of research, development and testing are much more numerous and much more rigorous than is perceived by the general public. Section 3.3 and Appendices 1, 11 and 12 also describe some of the many levels of controls placed on the BDRP Far from being almost unregulated, the program activities and procedures are heavily reviewed at every location where they are conducted.

Repugnance of Biological Warfare -- The U.S. government and the DoD share concerns over the potential consequences of biological warfare. This is why the U.S. was a lead negotiator in the development of the Biological Warfare Convention, which renounced storage and use of, and even research into biological weapons. It would be extremely desirable to develop some means whereby all nations could be totally assured that biological weapons would never be developed and used. However, such means have not yet been developed, and they may never be developed. Many nations have not signed the BWC, and it is always possible that some signatories could ignore its provisions. Thus, there exists the finite possibility that the U.S. and its Allies may encounter enemy use of biological weapons when and if troops must be deployed. The DoD strongly believes that it is necessary to have some defense against such weapons. Appendix l; contains the relevant portions of the text of the Biological Warfare Convention.

Overall, many of the concerns expressed during the scoping process (75) cannot be found to be based on the facts available. Strongly-held personal beliefs play an important role in shaping public concerns. Knowledge of the facts alone may not serve to alleviate every concern. To the extent that these concerns remain unresolved, they may be viewed as one specific form of public controversy, which has been discussed as an area of significant concern in sections 1.6.4 and 5.2.1, above, and acknowledged to be an area in which complete agreement may never be attained.

5.2.2.2 Program Benefits

Public Benefit

The infectious organisms and toxins of concern to the BDRP produce, or have produced, illness or death in naturally occurring episodes in one or more places throughout the world. BDRP developed drugs and vaccines thus have had, and can logically be expected to have, significant human and/or animal health and economic impacts, especially in those *parts* of the world where survival of food animals may mean the difference between life and death. Some recent examples are BDRP developed VEE vaccine used in Central America, Mexico, and Texas (1969 and Rift Valley Fever vaccine in Egypt and Central African Republic. In the epidemic of Venezuelan equine encephalomyelitis in the southern U.S. and Central America, the original outbreak of Legionnaires' disease in Philadelphia, and the outbreaks of Ebola fever, Lassa fever and Rift Valley fever in Africa, BDRP scientists led or were members of the specialized teams who pooled expertise in infectious diseases and coordinated the successful efforts that resulted in rapid and reliable diagnoses and, in some cases, countermeasures. In many of these outbreaks of enzootic disease, vaccines and/or hyperimmune plasma and/or antiviral drugs developed by the BDRP were used. BDRP-funded ribavirin (Virazoler) field trials are currently underway for treatment of naturally occurring hemorrhagic fever with renal syndrome (in the Republic of Korea and the People's Republic of China) and for Argentine hemorrhagic fever (in Argentina).

5.2.2.3 Human Health

General Population

The belief that there is a clear health hazard to the general population in the vicinity of locations performing BDRP research is not uncommon in some groups. The problem area here is seen to be one of perception versus reality. No incident may be found of an infection of a person not working in the research laboratory or other "at-risk" position in the 45-year history of US Army offensive and defensive RDT&E work (Appendix 8). The reasonableness of any contention that a civilian sector epidemic could easily result from an accident involving small laboratory quantities is examined in some detail in Appendix 9. For a variety of reasons, there is virtually no likelihood that large numbers of people would be likely to acquire any disease, nor is a person-to-person (communicable disease) spread likely. An examination of available data on BDRP-associated illness, infections, and accidents {see Appendix B) conducted for purposes of this EIS verified a total lack of credible hazard to the general public. The degree to which persons cannot be reassured of their personal safety represents an unresolved difference of opinion, which is examined is sections 5.2.1.3 and 5.2.2.1, above.

5.3 PRIMARY SITES

The primary sites of program execution are all located on active Army installations. They were identified (section 3.4) as those locations with either many ongoing efforts or with some responsibility for program planning and management or both. Examination of any site -specific topic at this programmatic level is restricted to relevant areas of environmental concern.

Further, certain areas of concern initially identif ied in this examination of the primary sites duplicated topics which have been examined above (section 5.2.1) as being correctly relevant only to the national environment. A more careful evaluation determined that these topics were a characteristic of the national environment, and were not actually generated by the site-specific actions. The site merely serves to focus some of the attention and concern created by the nationwide concerns and discussion. These topics were discussed in section 5.2.1, are identified here, and will not be individually examined again:

Program Management

Public Opinion: Controversial Issues

Program Benefits: National Defense Posture

Scientific Benefit

Public Benefit

5.3.1 USAMRIID

The U.S. Army Medical Research and Development Command's U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is physically located in Buildings 1425 and 1412 on Fort Detrick, adjacent to the city of Frederick in Frederick County, MD. Their mission under the BDRP is that of research and development of medical defenses against biological weapons.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of USAMRIID and its environment, including research-related health and safety provisions. See Appendix 6 for a complete examination of all relevant areas of potential concern.

5.3.1.1 Relevant Areas of Significant Concern

No unique areas.

5.3.1.2 Relevant Areas of Minor Concern

5.3.1.2.1 Surface Water

The water supply at Fort Detrick is good in terms of both quantity and quality. The current Fort Detrick Environmental Assessment (73) describes in detail the effect of daily post activities on the local water quality. Wastewater discharged from USAMRIID includes both laboratory and general wastewater discharges. Laboratory wastes are treated twice. They are first decontaminated before disposal in the laboratory and are then directed into a special collection and treatment system (see par 5.3.1.2.9 - Waste Stream Management) where they are sterilized prior to discharge to the installation sanitary sewer system. General wastewater discharge includes non-contaminated laboratory wastewater and sanitary sewer discharges. General wastewater, about 33% of the total wastewater from USAMRIID, is discharged directly into the Ft. Detrick sanitary sewer system for treatment in the installation wastewater treatment plant (73). See section 5.3.1.2.9, Waste Stream Management, for more details of wastewater treatment.

5.3.1.2.2 Biological Air Quality

The air quality at Fort Detrick is good, as is that of

APPENDIX H
PERMITS FROM POCONO TOWNSHIP HELD BY TSI-GSD

POCONO TOWNSHIP, MONROE COUNTY, PENNSYLVANIA

BUILDING & ZONING PERMIT

Fee:

Building Location: U.S. Route 611
(Street or L. R. Route No.)

Swiftwater, PA 18370
(City, State, Zip Code)

Date: July 18, 1989 Twp. Tax Map Code #: 12/12/2/10

Permit #: 3829

Name of Property Owner: The Salk Institute

Address of Property Owner: P.O. Box 250, Swiftwater, PA 18370

Phone 717-839-8863

Applicant hereby applies for a permit to: (Check appropriate blocks)

Erect a Structure		Permanent Home (Custom Built)	
Add to a Structure	X	Permanent Home (Factory Built)	
Alter a Structure		Second Home Winterized	
Change a Use		Second Home Non-Winterized	
		Mobile Home — Movable	

Estimated Cost of Proposed Work $ 4,623,400.

Remarks:

Please show sketch of lot on reverse side of all three copies.

1. Location of Lot
2. Location of Building on Lot
3. Approximate Lot Dimensions
4. Approximate Building Dimensions

Signature of Applicant George French

Address of Applicant P.O. Box 250
Swiftwater, PA 18370

Donald F. Wilson
(SIGNATURE OF APPROVING OFFICIAL)

017035

7/24/89 -
ck 350.00 to Jane

Distribution: Township; County Assessor; Owner

POCONO TOWNSHIP, MONROE COUNTY, PENNSYLVANIA

BUILDING & ZONING PERMIT

Fee:

Building Location: Route 611
(Street or L. R. Route No.)

Swiftwater, Pa. 18370
(City, State, Zip Code)

Date: 3/27/89 Twp. Tax Map Code #: 12-12-2-10

Permit #: 3769

Name of Property Owner: Salk Institute

Address of Property Owner: P.O.Box 250

Swiftwater,Pa. 18370 Phone (717)839-8865

Applicant hereby applies for a permit to: (Check appropriate blocks)

Erect a Structure		Permanent Home (Custom Built)	
Add to a Structure	XXXXXX	Permanent Home (Factory Built)	
Alter a Structure		Second Home Winterized	
Change a Use		Second Home Non-Winterized	
		Mobile Home — Movable	

Estimated Cost of Proposed Work $ 80,000.00

Remarks: Build as Presented in Site Plan

Please show sketch of lot on reverse side of all three copies. (SEE SITE PLAN)

1. Location of Lot
2. Location of Building on Lot
3. Approximate Lot Dimensions
4. Approximate Building Dimensions

Signature of Applicant [signature]

Address of Applicant Swiftwater Pa
18370

[signature]
(SIGNATURE OF APPROVING OFFICIAL)

Distribution: Township; County Assessor; Owner

POCONO TOWNSHIP

P. O. Box 207

U. S. 611 Tannersville, Pa. 18372

Phone: 629-1922

OCCUPANCY PERMIT

DATE 1/13/87 OCCUPANCY PERMIT NO. 1732

To: Salt Institute Owner

Address P.O. Box 250

Swiftwater, Pa. 18370

This is to certify that the property located at Mail Address Salt Institute - 410

Sq. Ft. warehouse addit - Swiftwater, Pa. 18370

Assessment Code number (from tax bill) 12-12-2-6 & 12

is in a I district and:

1. The completed premises of this property have been inspected by the inspector and all work undertaken has been found to comply with provisions of the Zoning Ordinance #16 and with the Zoning Permit No. 2990 issued on 11/5/86 19..........

2. An Occupancy Permit for the above property is hereby granted.

3. Remarks:

   (Time Limit)

, Zoning Officer

This certificate does not in any way relieve the owners, or any other person or persons in possession or control of the building, or any part thereof, from obtaining such other permits or licenses as may be prescribed by law for the uses or purposes for which the land or building is designed or intended, nor from complying with any lawful order issued with the object of maintaining the building or land in a safe or lawful condition.

POCONO TOWNSHIP
P. O. Box 207
U. S. 611 Tannersville, Pa. 18372
Phone: 629-1922

OCCUPANCY PERMIT

DATE 1/13/87 OCCUPANCY PERMIT NO. 1231

To: Salk Institute Owner

Address P.O. Box 250

Swiftwater Pa. 18370

This is to certify that the property located at Mail Address Salk Institute - 940

Sq. Ft. warehouse addt - Swiftwater Pa. 18370

Assessment Code number (from tax bill) 12-12-2-10 & 12

is in a I district and:

1. The completed premises of this property have been inspected by the inspector and all work undertaken has been found to comply with provisions of the Zoning Ordinance #16 and with the Zoning Permit No. 2662 issued on 6/18/85 19.........

2. An Occupancy Permit for the above property is hereby granted.

3. Remarks: ....

(Time Limit) ....

Zoning Officer

This certificate does not in any way relieve the owners, or any other person or persons in possession or control of the building, or any part thereof, from obtaining such other permits or licenses as may be prescribed by law for the uses or purposes for which the land or building is designed or intended, nor from complying with any lawful order issued with the object of maintaining the building or land in a safe or lawful condition.

POCONO TOWNSHIP

P. O. Box 207

U. S. 611 Tannersville, Pa. 18372

Phone: 629-1922

OCCUPANCY PERMIT

DATE 12/19/96 OCCUPANCY PERMIT NO. 1711

To: Salk Institute Owner

Address P.O. Box 250

Swiftwater PA 18370

This is to certify that the property located at Mail Address Salk Institute

Rt 611 Swiftwater PA 18370

Assessment Code number (from tax bill) 12-12-2-10-5-12

is in a I district and:

1. The completed premises of this property have been inspected by the inspector and all work undertaken has been found to comply with provisions of the Zoning Ordinance #16 and with the Zoning Permit No. 2924 issued on 9/8/96 19........

2. An Occupancy Permit for the above property is hereby granted.

3. Remarks:

   (Time Limit)

Zoning Officer

This certificate does not in any way relieve the owners, or any other person or persons in possession or control of the building, or any part thereof, from obtaining such other permits or licenses as may be prescribed by law for the uses or purposes for which the land or building is designed or intended, nor from complying with any lawful order issued with the object of maintaining the building or land in a safe or lawful condition.

POCONO TOWNSHIP, MONROE COUNTY, PENNSYLVANIA

BUILDING & ZONING PERMIT

Fee: 35.00

Building Location: Rt. 611 — Salk Institute
(Street or L. R. Route No.)

SWIFTWATER PA 18326
(City, State, Zip Code)

Date: 10/30/86 11/5/86 Twp. Tax Map Code #: 12-12-2-10 AND 12

Permit #: 2890

Name of Property Owner: SALK INSTITUTE GOVERNMENT SERVICE DIV.

Address of Property Owner: PO Bx 250 RT 611

SWIFTWATER PA 18392 Phone 839-7187

Applicant hereby applies for a permit to: (Check appropriate blocks)

Erect a Structure		Permanent Home (Custom Built)	
Add to a Structure	X	Permanent Home (Factory Built)	
Alter a Structure		Second Home Winterized	
Change a Use		Second Home Non-Winterized	
		Mobile Home — Movable	

Estimated Cost of Proposed Work $ 8,000.00

Remarks: 20' x 20' - 400 Sq. Ft. Addition - [illegible] Approved by Pocono Twp. - Occupancy Permit Notice Attached

Please show sketch of lot on reverse side of all three copies.

1. Location of Lot
2. Location of Building on Lot
3. Approximate Lot Dimensions
4. Approximate Building Dimensions

Signature of Applicant [signature]

Address of Applicant RD 1 Bx 319C Cresco

[signature]
(SIGNATURE OF APPROVING OFFICIAL)

Distribution: Township; County Assessor; Owner

TOWNSHIP, MONROE COUNTY, PENNSYLVANIA

BUILDING & ZONING PERMIT

Fee: 35.00

Building Location: RT 611
(Street or L. R. Route No.)

SWIFTWATER, PA 18326
(City, State, Zip Code)

8/27/86 ... 12-12-2-10 AND 12
9/5/86 ... 2924

Property Owner: SACK INSTITUTE GOVERNMENT SERVICES DIVISION

Address of Property Owner: PO BX 250 RT 611

SWIFTWATER PA 18370 Phone 839-7187

... permit is: (Check appropriate blocks)

New Structure		Permanent Home (Custom Built)	
... Structure	X	Permanent Home (Factory Built)	
... Structure		Second Home Winterized	
...nge a Use		Second Home Non-Winterized	
		Mobile Home — Movable	

...mated Cost of Proposed Work $ 63,000

...arks: 425 Sq Ft Addition as per plans approved by ... - Occupancy Permit Notice Attached

...show sketch of lot on reverse side of all three copies.

Location of Lot

Location of Building on Lot

3. Approximate Lot Dimensions

4. Approximate Building Dimensions

DRWG # A-3 REV. 7/7/86

Signature of Applicant [signature]

Address of Applicant RD 1 Box 319C

Cresco

....

POCONO TOWNSHIP, MONROE COUNTY, PENNSYLVANIA

BUILDING & ZONING PERMIT

Fee: 35.00

Building Location: Route 611
(Street or L. R. Route No.)

Swiftwater Pa 18370
(City, State, Zip Code)

Date: 6/18/85 Twp. Tax Map Code #: 12-12-2-10 & 12

Permit #: 2640

Name of Property Owner: Salk Institute

Address of Property Owner: Swiftwater
Pa 18370 Phone 839-8863

Applicant hereby applies for a permit to: (Check appropriate blocks)

Erect a Structure		Permanent Home (Custom Built)	
Add to a Structure	X	Permanent Home (Factory Built)	
Alter a Structure		Second Home Winterized	
Change a Use		Second Home Non-Winterized	
		Mobile Home — Movable	

Estimated Cost of Proposed Work $ 77,000.00

Remarks: 960 Sq. Ft. warehouse addition as per approved plans - Occupancy Permit + Notice Attached

Please show sketch of lot on reverse side of all three copies.

1. Location of Lot
2. Location of Building on Lot
3. Approximate Lot Dimensions
4. Approximate Building Dimensions

Signature of Applicant [signature]

Address of Applicant RT 611, Swiftwater
PA

[signature]
(SIGNATURE OF APPROVING OFFICIAL)

Distribution: Township; County Assessor; Owner

APPENDIX I
ANIMAL SPECIES POTENTIALLY INHABITING THE AREA AROUND TSI-GSD

Pennsylvania Fish and Wildlife Data Base
LIST A: Project Area Species List - MASTER LIST
** Environmental Assessment for Salk Institute Facility **
Monroe County
02 APR 1991

Note: The following species are likely to occur in or near the project area listed above. However, occurrence may depend on season, habitat type, and individual movements or migration patterns.

Land Use/Cover Types Included:

Urban - Residential
Urban - Commercial/Services
Rangeland - Mixed
Forest - Deciduous
Water - Streams/Canals
Wetland - Nonforested

Category	No. of Species Listed
FISH	38
AMPHIBIANS	23
REPTILES	22
BIRDS	212
MAMMALS	45
Total Species Listed	340

Pennsylvania Fish and Wildlife Data Base
LIST A: Project Area Species List - MASTER LIST
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Common Name	Scientific Name............................... ....
BASS, LARGEMOUTH	MICROPTERUS SALMOIDES
BASS, ROCK	AMBLOPLITES RUPESTRIS
BASS, SMALLMOUTH	MICROPTERUS DOLOMIEUI
BLUEGILL	LEPOMIS MACROCHIRUS
BULLHEAD, BROWN	ICTALURUS NEBULOSUS
BULLHEAD, YELLOW	ICTALURUS NATALIS
CARP, COMMON	CYPRINUS CARPIO
CHUB, CREEK	SEMOTILUS ATROMACULATUS
CHUBSUCKER CREEK	ERIMYZON OBLONGUS
CRAPPIE, BLACK	POMOXIS NIGROMACULATUS
DACE, BLACKNOSE	RHINICHTHYS ATRATULUS
DACE, LONGNOSE	RHINICHTHYS CATARACTAE
DARTER, SHIELD	PERCINA PELTATA
DARTER, TESSELLATED	ETHEOSTOMA OLMSTEDI
EEL, AMERICAN	ANGUILLA ROSTRATA
FALLFISH	SEMOTILUS CORPORALIS
KILLIFISH, BANDED	FUNDULUS DIAPHANUS
LAMPREY, SEA	PETROMYZON MARINUS
MADTOM, MARGINED	NOTURUS INSIGNIS
MINNOW, CUTLIPS	EXOGLOSSUM MAXILLINGUA
PERCH, YELLOW	PERCA FLAVESCENS
PICKEREL, CHAIN	ESOX NIGER
PICKEREL, REDFIN	ESOX AMERICANUS
PUMPKINSEED	LEPOMIS GIBBOSUS
SCULPIN, SLIMY	COTTUS COGNATUS
SHAD, AMERICAN	ALOSA SAPIDISSIMA
SHINER, BRIDLE	NOTROPIS BIFRENATUS
SHINER, COMMON	NOTROPIS CORNUTUS
SHINER, GOLDEN	NOTEMIGONUS CRYSOLEUCAS
SHINER, SATINFIN	NOTROPIS ANALOSTONUS
SUCKER, WHITE	CATOSTOMUS COMMERSONI
SUNFISH, BLUESPOTTED	ENNEACANTHUS GLORIOSUS
SUNFISH, GREEN	LEPOMIS CYANELLUS
SUNFISH, REDBREAST	LEPOMIS AURITUS
TROUT, BROOK	SALVELINUS FONTINALIS
TROUT, BROWN	SALMO TRUTTA
TROUT, RAINBOW	SALMO GAIRDNERI
WALLEYE	STIZOSTEDION VITREUM
BULLFROG	RANA CATESBEIANA
FROG, GREEN	RANA CLAMITANS
FROG, PICKEREL	RANA PALUSTRIS
FROG, UPLAND CHORUS	PSEUDACRIS TRISERIATA FERIARUM
FROG, WOOD	RANA SYLVATICA
NEWT, EASTERN	NOTOPHTHALMUS VIRIDESCENS
NEWT, RED-SPOTTED	NOTOPHTHALMUS VIRIDESCENS VIRID
PEEPER, NORTHERN SPRING	HYLA CRUCIFER

Pennsylvania Fish and Wildlife Data Base
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Common Name	Scientific Name............................... ....
SALAMANDER, FOUR-TOED	HEMIDACTYLIUM SCUTATUM
SALAMANDER, JEFFERSON	AMBYSTOMA JEFFERSONIANUM
SALAMANDER, LONGTAIL	EURYCEA LONGICAUDA
SALAMANDER, MARBLED	AMBYSTOMA OPACUM
SALAMANDER, MOUNTAIN DUSKY	DESMOGITHOS OCEROPHAEUS
SALAMANDER, NORTHERN DUSKY	DESMOGNATHUS FUSCUS FUSCUS
SALAMANDER, NORTHERN RED	PSEUDOTRITON RUBER RUBER
SALAMANDER, NORTHERN SPRING	GYRINOPHILUS PORPHYRITICUS PORP
SALAMANDER, NORTHERN TWO-LINED	EURYCEA BISLINEATA
SALAMANDER, REDBACK	PLETHODON CINEREUS
SALAMANDER, SLIMY	PLETHODON GLUTINOSUS
SALANANDER, SPOTTED	AMBYSTOMA MACULATUM
SPADEFOOT, EASTERN	SCAPHIOPUS HOLBROOKII
TOAD, AMERICAN	BUFO AME RICANUS
TOAD, FOWLER'S	BUFO WOODHOUSEI FOWLERI
COPPERHEAD, NORTHERN	AGEISTRODON CONTORTRIX
RACER	COLUBER CONSTRICTOR
RATTLESNAKE, TIMBER	CROTALUS HORRIDUS
SKINK,, FIVE-LINED	EUMECES FASCIATUS
SNARE, BLACK RAT	ELAPHE OBSOLETA
SNARE, BROWN	STORERIA DERAYI
SNAKE, COMMON GARTER	THAMNOPHIS SIRTALIS
SNAKE, EASTERN MILK	LANPROPELTIS TRIANGULUM
SNAKE, EASTERN RIBBON	THAMNOPHIS SAURITUS
SNAKE, NORTHERN RED-BELLIED	STORERIA OCCIPITOMACULATA
SNAKE, NORTHERN WATER	NERODIA SIPEDON SIPEDON
SNARE, RING-NECK	DIADOPHIS PUNCTATUS ARNYI
SNAKE, SMOOTH GREEN	OPHEODRYS VERNALIS
SNAKE, NORM	CARPHOPHIS AMOENUS
STINXPOT	STERNOTHERUS ODORATUS
TURTLE, BOG	CLEMMYS MUHLENBERGI
TURTLE, COMMON SNAPPING	CHELYDRA SERPENTINA -
TURTLE, EASTERN BOX	TERRAPENE CAROLINA
TURTLE, MIDLAND PAINTED	CHRYSEMYS PICTA MARGINATA
TURTLE, PAINTED	CHRYSEMYS PICTA
Tuttle, SPOTTED	CLEMMYS GUTTATA
TURTLE, WOOD	CLEMMY'S INSCULPTA
BITTERN, AMERICAN	BOTAURUS LENTIGINOSUS
BLACKBIRD, RED-WINGED	AGELAIUS PHOEN7CEUS
BLACKBIRD, RUSTY	EUPHAGUS CAROLINUS
BLUEBIRD, EASTERN	SIALIA SIALIS
BOBOLINK	DOLICHONYX ORYZIVORUS
BOBWHITE, NORTHERN	COLINUS VIRGINIANUS

Pennsylvania Fish and Wildlife Data Base
LIST A: Project Area Species List - MASTER LIST
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Common Name	Scientific Name.............................. ....
BUFFLEHEAD	BUCEPHALA ALBEOLA
BUNTING, INDIGO	PASSERINA CYANEA
BUNTING, SNOW	PLECTROPHENAX NIVALIS
CANVAS2ACR	AYTHYA VALISINERIA
CARDINAL, NORTHERN	CARDINAI,IS CARDINALIS
CATBIRD, GRAY	DUMETEI LA CAROLINENSIS
CHAT, YELLOW-BREASTED	ICTERIA VIRENS
CHICKADEE, BLACK-CAPPED	PARUS ATRICAPILLUS
CHICKADEE, CAROLINA	PARUS CAROLINENSIS
COOT, AMERICAN	FULICA AMERICANS
COWBIRD, BROWN-HEADED	OLOTEIRUS ATER
CREEPER, BROWN	CERTHIA AMERICANA
CROSSBILL, RED	LOXIA CURVIROSTRA
CROSSBILL, WHITE-WINGED	LOXIA LEUCOPTERA LEUCOPTERA
CROW, AMERICAN	Corvus BRACHNCHOS
CROW, FISH	Corvus OSSIFRAGUS
CUCKOO, BLACK-BILLED	COCCYZUS ERYTHROPTHALMUS
CUCKOO, YELLOW-BILLED	COCCYZUS AMERICANUS
DICRCISSEL	SPIZA AMERICANA
DOVE, MOURNING	ZENAIDA MACROURA
DOVE, ROCK	COLUMBA LIVIA
DOWITCHER, SHORT-BILLED	LIMNODRONUS GRISEUS
DUCK, AMERICAN BLACK	ANAS RUBRIPES
DUCK, RING-NECKED	AYTHYA COLLARIS
DUCK, RUDDY	OXYURA JANAICENSIS
DUCK, WOOD	AIX SPONSA
DUNLIN	CALIDRIS ALPINA
EAGLE, BALD	HALIAEETUS LEUCOCEPHALUS
EAGLE, GOLDEN	AQUILA CHRYSAETOS
FALCON, PEREGRINE	FALCO PEREGRINUS TUNDRIUS
FINCH, HOUSE	CARPODACUS MEXICANUS
FINCH, PURPLE	CARPODACUS PURPUREUS
FLICKER, NORTHERN	COLAPTES AURATUS
FLYCATCHER, ACADIAN	EUPIDONAX VIRESCENS
FLYCATCHER, GREAT CRESTED	MYLARCHUS CRINITUS
FLYCATCHER, OLIVE-SIDED	CONTOPUS BOREALIS
FLYCATCHER, WILLOW	EMPIDONAX TRAILLII
FLYCATCHER, YELLOW-BELLIED	EMPIDONAX FLAVIVENTRIS
Gad wall	ANAS STREPERA
GNATCATCHER, BLUE-GRAY	POLIOPTILA CAERULEA
GOLDENEYE, COMMON	BUCEPHALA CLANGULA
GOLDFINCH, AMERICAN	CARDUELIS TRISTIS
GOOSE, CANADA	BRANTA CANADENSIS
GOSHAWK NORTHERN	ACCIPITER GENTILIS
GRACRLE, COMMON	QUISCALUS QUISCULA
GREBE, PIED-BILLED	PODILYMBUS PODICEPS
GROSBEAK, BLUE	GUIRACA CAERULEA
GROSBEAK, EVENING	COCCOTHRAUSTES VESPERTINUS
GROSBEAK ROSE-BREASTED	PHEUCTICUS LUDOVICIANUS

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Common Name	Scientific Name.............................. ....
GROUSE, RUFFED	BONASA UMBELLUS
GULL, BONAPARTE'S	LARUS PHILADELPHIA
GULL, HERRING	LARUS ARGENTATUS
GULL, LAUGHING	LARUS ATRICILLA
GULL, RING-BILLED	LARUS DELAWARENSIS
HARRIER, NORTHERN	CIRCUS CYANEUS
HAWK BROAD-WINGED	BUTEO PLATYPTERUS
HAWK, COOPER'.S	ACCIPITER COOPERII
MAWR, RED-SHOULDERED	BUTEO LINEATUS
HAWK RED-TAILED	BUTEO JAMAICENSIS
HAWK, ROUGH-LEGGED	BUTEO LAGOPUS
HAWK, SHARP-SHINNED	ACCIPITER STRIATUS
HERON, GREEN-BACKED	BUTORIDES STRIATUS
HERON, LITTLE BLUE	FLORIDA CAERULEA
HUMMINGBIRD, RUBY-TXROATED	ARCHILOCHUS COLUBRIS
IBIS, GLOSSY	PLEGADIS FALCINELLUS
JAY, BLUE .	CYANOCITTA CRISTATA
JUNCO, DARK-EYED	JUNCO HYEMALIS
KESTREL, AMERICAN	FALCO SPARVERIUS
RILLDEER	CHARADRIUS VOCIFERUS
KINGBIRD, EASTERN	TYRANNUS TYRANNUS
KINGFISHER, BELTED	CERYLE ALCYON
RINGLET, GOLDEN-CROWNED	REGULUS SATRAPA
RINGLET, RUBY-CROWNED	REGULUS CALENDULA
LARK, HORNED	EREMOPHILA ALPESTRIS PRATICOLA
MALLARD	ANAS PLATYRHYNCHOS
MARTIN, PURPLE	PROGNE SUBIS
MEADOWLARR, EASTERN	STURNELLA MAGNA
MERGANSER, COMMON	MERGUS MERGANSER
MERGANSER, HOODED	LOPHODYTES CUCULLATUS
MERLIN	FALCO COLUMBARIUS
MOCRINGBIRD,.NORTHERN	MINUS POLYGLOTTOS
MOORHEN, COMMON	GALLINULA CHLOROPUS
NIGHTHANR, COMMON	CHORDEILES MINOR
NUTHATCH, WHITE-BREASTED	SITTA CAROLINENSIS
ORIOLE, NORTHERN	ICTERUS GALBULA
ORIOLE, ORCHARD	ICTERUS SPURIUS
OSPREY	PANDION HALIAETUS
OVENBIRD	SEIURUS AUROCAPILLUS
OWL, BARRED	STRIX VARIA
OWL, EASTERN SCREECH	OTUS ASIO
OWL, GREAT HORNED	BUBO VIRGINIANUS
OWL, LONG-EARED	OTUS ASIO
OWL, NORTHERN SAW-WHET	AEGOLIUS ACADICUS
OWL, SHORT-EARED	ASIO FLAMMEUS
PEWEE, EASTERN WOOD	CONTOPUS VIRENS
PHALAROPE, RED-NECKED	PHALAROPUS LOBATUS
PHEASANT, RING-NECKED	PHASIANUS COLCHICUS
PHOEBE, EASTERN	SAYORNIS PHOEBE

Pennsylvania Fish and Wildlife Data Base
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Common Name	Scientific Name.............................. ....
PLOVER, BLACK-BELLIED	PLUIALIS SQUATAROLA
PLOVER, LESSER-GOLDEN	PLUIALIS DOMINICA
PLOVER, SEMIPALMATED	CHARADRIUS SEMIPALMATUS
RAIL, KING	RALLUS ELEGANS
RAIL, VIRGINIA	RALLUS LIMICOLA
REDHEAD	AYTHYA AMERICANA
REDPOLL, COMMON	CARDUELIS FLAMMEA
REDSTART, ANERICAN	SETOPHAGA RUTICILLA
ROBIN, AMERICAN	TURDUS MIGRATORIUS
SANDPIPER, PECTORAL	CALIDRIS MELANOTOS
SANDPIPER, SENIPALMATED	CALIDRIS PUSILLA
SANDPIPER, SOLITARY	TRINGA SOLITARIA
SANDPIPER, SPOTTED	ACTITIS MACULARIA
SANDPIPER, UPLAND	BATRAMIA LONGICAUDA
Sapsucker, YELLOW-BELLIED	SPHYRAPICUS VARIUS
SCAUP, GREATER	AYTHYA MARILA
SCAUP, LESSER	AYTHYA AFFINIS
SCOTER, Black	MELANITTA NIGRA
SHRIRE, LOGGERHEAD	LANIUS LUDOVICIANUS
SHRIKE, NORTHERN	LANIUS EXCUBITOR
SNIPE, COMMON	GALLINAGO GALLINAGO
SORA	PORZANA CAROLINA
SPARROW, AMERICAN TREE	SPIZELLA ARBOREA
SPARROW, CHIPPING	SPIZELLA PASSERINA
SPARROW, FIELD	SPIZELLA PUSILIA
SPARROW, FOX	PASSERELLA ILIACA
SPARROW, HENSLOW'S	ANMODRAMUS HENSLOII
SPARROW, HOUSE	PASSER DOMESTICUS
SPARROW, LINCOLN'S	MELOSPIZA LINCOLNII
SPARROW, SONG	MELOSPIZA MELODIA
SPARROW, SWAMP	MELOSPI2A GEORGIANA
SPARROW, WHITE-CROWNED	ZONOTRICHIA LEUCOPHRYS
SPARROW, WHITE-THROATED	ZONOTRICHIA ALBICOLLIS
STARLING, EOROPEAN	STURNUS WLGARIS
SWALLOW, BANK	RIPARIA RIPARIA
SWALLOW, BARN	HIRUNDO RUSTICA
SWALLOW, CLIFF	HIRUNDO PYRRHONOTA
SWALLOW, NORTHERN ROUGH-WINGED	STELGIWPTERYX SERRIPENNIS
SWALLOW, TREE	TACHYCINETA BICOLOR
SWAN, MUTE	CYGNUS OLOR
SWIFT, CHIMNEY	CHAETURA PELAGICA
TANAGER, SCARLET	PIRANGA OLIVACEA
TANAGER, SUMMER	PIRANGA RUERA
TEAL, BLUE-WINGED	ANAS DISCORS
TEAL, GREEN-WINGED	ANAS CRECCA
TERN, BLACK	CHLIDONIAS NIGER
TERN, COMMON	STERNA HIRUNDO
THRASHER, BROWN	TOXOSTONA RUFUM
THRUSH GRAY-CHEEICED	CATHARUS MINIMUS

Pennsylvania Fish and Wildlife Data Base
LIST A: Project Area Species List - MASTER LIST
** Environmental Assessment for Salk Institute Facility **
Monroe County
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Common Name	Scientific Name.............................. ....
THRUSH, HERMIT	CATHARUS GUTTATUS
THRUSH, SWAINSON'S	CATHARUS USTULATUS
THRUSH, WOOD	HYLOCICXLA MUSTELINA
TITMOUSE, TU FTED	PARUS BICOLOR
TOWHEE, RUFOUS-SIDED	PIPILO ERYTHROPHTHALMUS
TURREY, WILD	MELEAGRIS GALLOPAVO
VEERY	CATHARUS FUSCESCENS
VIREO, PHILADELPHIA	VIREO PRILADELPHICUS
VIREO, RED-EYED	VIREO OLIVACEUS
VIREO, SOLITARY	VIREO SOLITARIUS
VIREO, WARBLING	VIREO GIL S
VIREO, WHITE-EYED	VIREO GRISEUS
VIREO, YELLOW-THROATED	VIREO FLAVIFRONS
VULTURE, BL ACK	CORAGYPS ATRATUS
VULTURE TURKEY	CATHARTES AURA
WARBLER, BAY-BREASTED	DENDROICA CASTANA
WARBLER, BLACK-AND-WHITE	MNIOTILTA VARIA
WARBLER, BLACR-THROATED BLUE	DENDROICA CAERULESCENS
WARBLER, BLACX-THROATED GREEN	DENDROICA VIRENS
WARBLER, BLACR3URNIAN	DENDROICA FUSCA
WARBLER, BLACKPOLL	DENDROICA STRIATA
WARBLER, BLUE-WINGED	VERMIVORA PINUS
WARBLER, CANADA	WILSONIA CANADENSIS
WARBLER, CAPE MAY	DENDROICA TIGRINA
WARBLER, CERULEAN	DENDROICA CERULEA
WARBLER, CHESTNUT-SIDED	DENDROICA PENNSYLVANICA
WARBLER, GOLDEN-WINGED	VERMIVORA CHRYSOPTERA
WARBLER, HOODED	WILSONIA CITRINA
WARBLER, MAGNOLIA	DENDROICA MAGNOLIA
WARBLER, MOURNING	OPORORNIS PHILADELPHIA
WARBLER, NASHVILLE	VERMIVORA RUFICAPILLA
WARBLER, NORTHERN PARULA	PARULA AMERICANA
WARBLER, PINE	DENDROICA PINUS
WARBLER, PRAIRIE	DENDROICA DISCOLOR
WARBLER, PROTHONOTARY	PROTONOTARIA CITREA
WARBLER, TENNESSEE	VERMIVORA PEREGRINA
WARBLER, WILSON'S	WILSONIA PUSILLA
WARBLER, WORN-EATING	HELNITHEROS VERMIVORUS
Warbler, YELLOW	DENDROICA PETECHIA
WARBLER, YELLOW-RUMPED	DENDROICA CORONATA
WARBLER, YELLOW-THROATED	DENDROICA DOMINICA
WATERTHRUSH, LOUISIANA	SEIURUS MOTACILLA
WATERTHRUSH, NORTHERN	SEIURUS NOVEBORACENSIS
WAXWING, CEDAR	BOMBYCILLA CEDRORUM
WHIP-POOR-WILL	CAPRIMULGUS VOCIFERUS
WIGEON, AMERICAN	ANAS ANERICANA
WOODCOCK, AMERICAN	SCOLOPAX MINOR
WOODPECKER, DOWNY	PICOIDES PUBESCENS
WOODPECKER, HAIRY	PICOIDES VILLOSUS

Pennsylvania Fish and Wildlife Data Base
LIST A: Project Area Species List - MASTER LIST
** Environmental Assessment for Salk Institute Facility **
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Common Name	Scientific Name.............................. ....
WOODPECKER, PILEATED	DRYOCOPUS PILEATUS
WOODPECKER, RED-BELLIED	MELANERPES CAROLINUS
WOODPECKER, RED-HEADED	MELANERPES ERYTHROCEPHALUS
WREN, CAROLINA	TXRYOTHORUS LUDOVICIANUS
WREN, HOUSE	TROGLODYTES AEDON
WREN, MARSH	CISTOTHORUS PALUSTRIS
WREN, WINTER	TROGLODYTES TROGLODYTES
YELLOWLEGS, GREATER	TRINGA MELANOLEUCA
YELLOULEGS, LESSER	TRINGA FLAVIPES
YELLOWTHROAT, COMMON	GEOTHLYPIS TRICHAS BRACHIDACYY
BAT, BIG BROWN	EPTESICUS FUSCUS
BAT, HOARY	LASIURUS CINEREUS
BAT, RED	LASIURUS BOREALIS.
BEAR, BLACK	URSUS AMERICANUS
BEAVER	CASTOR CANADENSIS
BOBCAT	FELIS RUFUS
CHIPMUNK, EASTERN	TAMIAS STRIATUS
COTTONTAIL, EASTERN	SYLVILAGUS FLORIDANUS
COYOTE	CANIS LATRANS
DEER, WRITE-TAILED	ODOCOILEDS VIRGINIANUS
ERMINE	MUSTELA ERMINES CICOGNANII
FOX, GRAY	UROCYON CINEREOARGENTEUS
FOX, RED	vuPES VU LPES
HARE, SNOWSHOE	LEPUS AMERICANUS
LEMMING, SOUTHERN BOG	SYNAPTOMYS COOPERI
MINK	MUSTELA VISON
MOLE, EASTERN	SCALOPUS AQUATICUS
MOLE, HAIRY-TAILED	PARASCALOPS BREWERI
MOLE, STAR-NOSED	CONDYLURA CRISTATA
MOUSE, DEER	PEROMYSCUS MANICULATUS
MOUSE, HOUSE	MUS MUSCULUS
MOUSE, MEADOW JUMPING	ZAPUS HUDSONIUS
MOUSE, WHITE-FOOTED	PEROMYSCUS LEUCOPUS
MOUSE, WOODLAND JUMPING	NAPAEOZAPUS INSIGNIS
MUSKRAT	ONDATRA ZIBETHICUS
MYOTIS, LITTLE BROWN	MYOTIS LUCIFUGUS
OPOSSUM, VIRGINIA	DIDELPHIS VIRGINIANA
OTTER, RIVER	LUTRA CANADENSIS
PIPISTRELLE, EASTERN	PIPISTRELLUS SUBFLAVUS
PORCUPINE	ERETHIZON DORSATUM
RACCOON	PROCYON LOTOR
RAT, NORWAY	RATTUS NORVEGICUS
SHREW, MASKED	SOREX CINEREUS
SHREW, NORTHERN SHORT-TAILED	BLARINA BREVICAUDA
SHREW, SMOKY	SOREX FUMEUS
SHREW, WATER	SOREX PALUSTRIS

Pennsylvania Fish and Wildlife Data Base
LIST A: Project Area Species List - MASTER LIST
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Common Name	Scientific Name
SKUNK, STRIPED	MEPHITIS MEPHITIS
SQUIRREL, GRAY	SCIURUS CAROLINENSIS
SQUIRREL, NORTHERN FLYING	GLAUCOMYS SABRINUS
SQUIRREL, RED	TANIASCIURUS HUDSONICUS
SQUIRREL, SOUTHERN FLYING	GLAUCOMYS VOCANS
VOLE, MEADOW	MICROTUS PENNSYLVANICUS
VOLE, WOODLAND	MICROTUS PINETORUM
WEASEL, LONG-TAILED	MUSTELA FRENATA
WOODCHUCK	MARMOTA MONAX

Pennsylvania Fish and Wildlife Data Base
LIST B: Endangered and Threatened Species List
** Environmental Assessment for Salk Institute Facility **
Mount Pocono Quadrangle
02 APR 1991

Note: The following species are likely to occur in or near the project areas listed above. However, occurrence may depend on season, habitat type, and individual movements or migration patterns.

Land Use/Cover Types Included:

Urban - Residential
Urban -Commercial/Services
Rangeland - Mixed
Forest - Deciduous
Water - Streams/Canals
Wetland - Nonforested

Common Name	Scientific Name	Status
TURTLE, BOG	CLEMMYS MUHLENBERGI	PA Endangered
BITTERN AMERICAN	BOTAURUS LENTIGINOSUS	PA Threatened

Pennsylvania Fish and Wildlife Data Base
LIST C: Endangered, Threatened, and Special Concern Species List
(Includes Accidental and Migrant Species)
** Environmental Assessment for Salk Institute Facility **
Monroe County
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Note: The following list includes species occurring in your project area as well as species which may accidentally occur but do not nest or rear young at or near your project site.

Land Use/Cover Types Included:

Urban - Residential
Urban - Commercial/Services
Rangeland - Mixed
Forest - Deciduous
Water - Streams/Canals
Wetland - Nonforested

Common Name	Scientific Name	Status
EAGLE, BALD	HALIAEETUS LEUCOCEPHALUS	PA/Fed Endangered
FALCON, PEREGRINE	FALCO PEREGRINUS TUNDRIUS	PA / Fed Endangered
TURTLE, BOG	CLEMMYS MUHLENBERGI	PA Endangered
OSPREY	PANDION HALIAETUS	PA Endangered
OWL, SHORT-EARED	ASIO FLAMMEUS	PA Endangered
RAIL, RING	RALLUS ELEGANS	PA Endangered
TERN, BLACK	CHLIDONIAS NIGER	PA Endangered
BITERN, AMERICAN	BOTAURUS LENTIGINOSUS	PA Threatened
FLYCATCHER,YELLOW-BELLIED	EMPIDONAX FLAVIVENTRIS	PA Threatened
SANDPIPER, UPLAND	BATRAMIA LONGICAUDA	PA Threatened
BLUEBIRD, EASTERN	SIALIA SIALIS	PA Special Concern Species
BOBWHITE, NORTHERN	COLINUS VIRGINIANUS	PA Special Concern Species
HARRIER, NORTHERN	CIRCUS CYANEUS	PA Special Concern Species
MAWR, COOPER'S	ACCIPITER COOPERII	PA Special Concern Species
HAWK, RED-SHOULDERED	BUTEO LINEATUS	PA Special Concern Species
ERON, GREAT BLUE	ARDEA HERODIAS	PA Special Concern Species
MARTIN, PURPLE	PROGNE SUBIS	PA Special Concern Species
SPARROW, HENSLOW'S	AMMODRAMUS HENSLOWII	PA Special Concern Species
WOODPECKER, RED-HEADED	MELANERPES ERYTHROCEPHALUS	PA Special Concern Species
WREN, MARSH	CISTOTHORUS PALUSTRIS	PA Special Concern Species
BOBCAT	FELIS RUFUS	PA Special Concern Species
HARE SNOWSHOE	LEPUS AMERICANUS	PA Special Concern Species
OTTER, RIVER	LUTRA CANADENSIS	PA Special Concern Species

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APPENDIX J
IDENTIFICATION OF RELEVANT AND SIGNIFICANT ISSUES TAKEN FROM THE BDRP FPEIS, APPENDIX 6

APPENDIX 6 IDENTIFICATION OF RELEVANT AND SIGNIFICANT ISSUES

CONTENTS

SECTION

1. INTRODUCTION

2. NEPA REQUIREMENTS

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4. IMPACT ANALYSIS MATRIX (IAM)

   4.1 Development of the IAM
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      4.2.1 Activities
      4.2.2 Controls
      4.2.3 Potential Areas Impacted
      4.2.4 Risks
      4.2.5 Relevant Areas Of Concern
   4.3 Matrix Application

5. IAM APPLICATION TO THE BDRP

6. EVALUATION OF FUTURE BDRP ACTIVITIES

1. INTRODUCTION

CEQ regulations (40CFR 1501.1) require early identification of significant environmental issues deserving study, as well as recommending the Reemphasis of insignificant issues, thus focusing the scope of an EIS. Both CEQ (40CFR 1500-1508) and Army (32CFR 651) regulations instruct proponents to identify and to eliminate insignificant issues from detailed study. The Biological Defense Research Program (BDRP) EIS team applied the scoping process outlined in 40CFR 1501.7 in order to identify the relevant issues and to eliminate issues of no concern. An interdisciplinary approach was used to ensure that relevant or significant issues would not be overlooked and that the EIS would emphasize relevant environmental issuer. Because of the highly technical and complex nature of the BDRP, special emphasis was placed on the scoping process to ensure that all relevant areas of environmental concern were identified. These concerns were then compiled into a master list of potential areas impacted by the BDRP. The resources and the process used to identify the relevant or significant issues are described in the following paragraphs.

2. NEPA REQUIREMENTS

The BDRP EIS team reviewed both NEPA and the CEO regulations to identify the areas of environmental concern that must normally be addressed in an EIS. The regulations require that certain issues, such as endangered species, public health and safety, must always be examined. To assure a comprehensive list for later screening, all of the areas for which consideration is mandated were listed without regard to any a priori opinions as to the significance or insignificance of potential impacts.

3. ISSUE IDENTIFICATION

3.1 SCOPING PROCEDURES

Measures outlined for the scoping process in the CEQ Regulations (40CFR 1501.7) were used to provide an opportunity for potentially concerned Federal, State, and local agencies: public interest groups; and other interested parties to participate in the identification of relevant or significant issues relating to the BDRP (l). Two scoping meetings were held in Tysons Corner, Virginia, on August 12, 1987 (2). Five individuals made presentations at these meetings. In addition, nineteen written statements and letters were submitted. The comments brought forth during the scoping process were reviewed by the EIS team and additional issues identified by the scoping participants were added to the list.

3.2 EICS MODEL

The Environmental Impact Computer System (EICS), (3) is a computer analysis system developed by the U.S. Army Construction

Engineering Research Laboratory (USACERL) to direct the EIS preparer's attention to those elements of the environment considered most likely to be affected by an Army action. The EICS is designed to consider nine functional areas of military activities. The broad functional area "Research, Development, Test and Evaluation" was selected as the area most germane to the BDRP. Environmental considerations for each of the functional areas are subdivided into thirteen technical specialties, from which the eight most pertinent to the BDRP were selected. These eight areas were health and safety, ecology, surface water, ground water, air quality, transportation, sociology, and economics. Output from EICS was then used to identify additional relevant areas of potential impact, which were added to the list.

3.3 OTHER DOCUMENTS

Additional issues or areas of potential environmental impact were identified by reviewing documents such as *Foundation on Economic Trends, et al., v. Caspar W. Weinberger, et al.,* Civil action 86-2436, filed February 12, 1987, in the U.S. District Court of the District of Columbia (4), the first amended complaint in the case of *Foundation on Economic Trends v. Weinberger,* Civil Action No. 86-2436, filed on September 29, 1986 in the U.S. District Court for the District of Columbia, t5), the Interrogatories (6), the "Final Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules" (7), the "Draft Environmental Assessment for Construction of and Lease of Land for the USAMRDC's Medical Research Institute of Toxinology, Fort Detrick, Maryland" (8), the "Draft Environmental Impact Statement, Biological Aerosol Test Facility, Dugway Proving Ground, Utah" (9), the "Working Paper Draft, Operational Environmental Assessment, Chemical Research, Development, and Engineering Center, Aberdeen Proving Ground, Maryland" (10), the "Memorandum Opinion and Order, *Foundation on Economic Trends v. Caspar W. Weinberger, et al.* (11), and the "Biosafety in Microbiological and Biomedical Laboratories" (12), etc.

4. IMPACT ANALYSIS MATRIX (IAM)

4.1 DEVELOPMENT OF THE IAM

The BDRP includes a broad set of technical and administrative functions conducted at numerous facilities. To apply the NEPA process efficiently to this extensive program, the EIS team developed a BDRP-specific analytical approach; the Impact Analysis Matrix (IAM). The IAM forced a systematic, comprehensive examination of all of the potential impacts of the BDRP, evaluated in light of the elements influencing those impacts. The matrix approach produced more than merely a "checklists because it encouraged a searching, realistic look at every interaction of activity and environment for potential impacts or hazards with reasoned thought and analysis. The result has been an exhaustive consideration and full disclosure of the potential environmental impacts associated with this program.

4.2 MATRIX DESIGN

The IAM was designed to display graphically program activities, controls exerted upon those activities, areas of the biophysical and socioeconomic environment that might be impacted, relevant areas of concern, and perceived and actual risks associated with the program. Descriptions of these elements as applied within the IAM are given below. At the same time, the application of the IAM to the programmatic areas and to individual sites served as documentation of the EIS team's consideration and analysis of the potential environmental impacts of the total BDRP.

4.2.1 ACTIVITIES

The activities conducted within the BDRP were grouped as laboratory and field (Research, Development, Test and Evaluation) and non-laboratory (Administration and Management) related endeavors. Each of these broad categories was further subdivided into more discrete task areas that could be evaluated individually for potential impacts on the identified areas of environmental concern. These activities and their major components are listed on Attachment I and discussed in section 3.2 of the EIS. *

4.2.2 CONTROLS

The major operational, safety, security, and regulatory controls under which BDRP activities are conducted are identified and defined on Attachment II and discussed in section 3.3.

4.2.3 POTENTIAL AREAS IMPACTED

The BDRP EIS Team developed a comprehensive list, through the method described in the foregoing discussion of issues and concerns, and added others based upon their experience and expertise. This completed list of issues was then grouped into two major elements of the environment, the biophysical and the socioeconomic. Fifteen categories of areas potentially impacted were then formulated and further subdivided to provide greater specificity. These categoric. and sub-categories were thoroughly reviewed by the EIS team to ensure that all previously identified issues could be addressed within one of the categoric. These fifteen categories, listed in Attachment III, define the relevant potential areas impacted by the BDRP.

*All references to "section" refer to information in the body of the EIS.

4.2.4 RISKS

Many of the issues and concerns raised during the public scoping process dealt with the potential for risks to the environment arising from the many activities conducted within the BDRP. Thus, the IAM was designed to identify perceived and actual risks for each activity conducted, as well as perceived and actual risk to each area of environment.

4.2.5 RELEVANT AREAS OF CONCERN

Identification of the significant and minor relevant areas of concern is the ultimate result of application of the IAM. Note that both the relevant area" of environmental concern as well as the activities that create these concerns are identified. By virtue of this thorough analysis, this process also identifies areas which will not be impacted, or only minimally impacted. This allows appropriate attention to be focused on the potentially significant issues and concerns and eliminates the others from unwarranted detailed coverage.

4.3 MATRIX APPLICATION .

Use of the IAM forced a multi-dimensional evaluation of each program activity. A systematic examination of each potential issue or impact, by an interdisciplinary team approach, ensured a more comprehensive scrutiny than any one individual was capable of providing. The different perspectives and areas of expertise were brought to bear in a synergistic fashion, such that the composite view represents a more thorough, "hard look" than can a number of separate individual opinions. Thus, the objective of identifying significant issues related to a proposed action, as expressed in 40CFR 1501.7, was achieved by the exhaustive and pragmatic analytical process of a scientific, interdisciplinary application of the IAM.

In order to provide an understanding of how the IAM was used, a sample "walk thru" is presented below. The application of the IAM involves selection of an activity (e.g. laboratory work, storage, etc.) to be evaluated. Each type of activity involves tasks or elements which have differing potential for impacts. The activity is then reviewed in relation to each of the four categories of controls (operational, safety, security, and regulatory) to determine which controls are applicable. A check mark indicates that a control is applicable. A knowledge of the nature of typical controls, and their respective effectiveness and limitations, is implicit in this application. The activity is then identified as either presenting a perceived or an actual risk, or both. The degree of risk is classified as being high or low.

Based on the above information, an assessment of the relative impact (high or low and adverse or positive) for each of the potential areas impacted is made. A blank indicates that an activity does not measurably affect a particular area of potential concern. Finally, a determination is made as to whether the effect is of relevant concern. This involves a reasoned judgement by the interdisciplinary evaluators, who used a synoptic consideration of the pertinent aspects from the matrix, along with other data such as quantities involved, past experiences, and any special circumstances which may be present. The activity is then specified as being either a minor or significant relevant area of concern, or neither. The IAM is completed in a similar manner for the remaining activities. Once all the applicable activities have been evaluated in the vertical direction, each potential area impacted (row of the matrix core) is reviewed for cumulative risks across the horizontal axis of the matrix. This provides an evaluation of risk (high, low or none) from BDRP activities to the potential area impacted. Furthermore, an evaluation is made to determine whether the risks should be classified as actual or perceived, or both, and to what degree. Next, a determination is made of the significance of the impacts or concerns for each of the potential areas impacted. This involves a synthesis by the interdisciplinary team of all available information into an informed judgement. An evaluation of the context and intensity, as defined in 40CFR 1508.27, of each impact or concern guides this assessment and judgement. Again, the impacts or concerns are determined to be either minor, significant, or neither. All of the activities and potential areas impacted are analyzed in this fashion to complete the IAM.

The background and basis for developing the IAM is helpful when considering its application. Particular attention must be paid to such factors as the potential hazards involved, and the magnitude, duration, degree, and severity of possible consequences when ascribing a-relative level of potential impact, or concern, upon an area impacted. Other considerations such as relative importance, scarcity, uniqueness, etc., of the resources must be analyzed as well. Proper use of the IAM requires sound, professional judgement to achieve meaningful results. It should also be understood that consideration of the "existing" situation or resource base includes consideration of foreseeable future change. that might affect the quality of a resource. Thus, a knowledge and understanding of both the areas or resources which could potentially be impacted, and the manner in which the program element or activity could cause impacts, are necessary ingredients for proper application of the IAM.

The completed IAM provides a thorough, systematic, interdisciplinary analysis of the potential effects of the BDRP activities on the human environment. It is used to identify the areas of significant environmental concern that are emphasized in the EIS. It also identifies the issues that are not significant and are thereby eliminated from detailed study. The risk assessment, by activity and potential area impacted, was useful in developing accident or incident scenarios for further evaluation, (Appendix 9). The existence of perceived risks, which are not substantiated by credible scientific evidence, indicates a need to provide more, or better, information to the public. Identification of activities as either minor or significant concerns also served to focus the analyses presented in the EIS.

5. IAM APPLICATION TO THE BDRP

The site-specific activities of the BDRP group naturally into primary and secondary sites. The functional, or programmatic aspects of the BDRP, are grouped into seven risk and/or issue categories. Detailed descriptions of the primary and secondary sites and programmatic categories are presented in the body of the DEIS (see sections 2.4, 2.5, 3.5, and appendices 3, 4 and 5). The EIS team applied IAM evaluations to each of the sites and to each of the programmatic categories using the described methodology. The results of these evaluations led to an identification of the relevant areas of concern addressed in this DEIS and to the elimination of insignificant issues from further consideration.

The sites and programmatic areas analyzed using the IAM's are listed below, and the results of the IAM evaluations, along with summaries are contained in Attachment IV.

Primary Sites		FIGURE
1.	U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) Frederick, MD	A6-1
2.	U.S. Army Chemical Research, Development and Engineering Center (CRDEC) Aberdeen Proving Ground, MD	A6-2
3.	U.S. Army Dugway Proving Ground (DPG) Dugway, UT	A6-3
Secondary Sites* (selected)		
4.	Jefferson Medical College Philadelphia, PA	A6-4
5.	SRI International Menlo Park, CA	A6-5
6.	Wright State University Dayton, OH	A6-6
7.	The Salk Institute, Government Services Division (TSI, GSD),Swiftwater, PA	A6-7
8.	Southern Research Institute (SoRI) Birmingham, AL	A6-8

9. Scripps Clinic and Research Foundation A6-9
La Jolla, CA

10. New York State Department of Public Health A6-10
Albany, NY

11. University of Massachusetts A6-11
Amherst, MA

12. Salk Institute A6-12
La Jolla, CA

Programmatic Evaluation

13. High Hazard Organisms A6-13

14. Low Hazard Organisms A6-14

15. Toxins A6-15

16. Genetically Engineered Microorganisms (GEMs) A6-16

17. Rapid Diagnosis and Detection A6-17

18. Vaccine and Drug Therapy Development A6-18

19. Other Program Research and Activities A6-19

* For a listing of all secondary sites, see Appendix 3.

6. EVALUATION OF FUTURE BDRP ACTIVITIES

This FEIS has been prepared as a programmatic environmental analysis in keeping with the guidance provided in 32CFR 651 and 4OCFR 1502.4(c), and will serve as a basis for tiering of future analyses and NEPA documents for proposed future activities of the BDRP.

From a programmatic viewpoint, it has been determined that the most significant issues and environmental concerns arise from the procedures associated with high hazard infectious organisms GEMs, and toxins. Impacts associated with all other program areas are insignificant. Thus, a tiering approach can be utilized to examine proposed changes to the BDRP or future activities. The requirement for separate NEPA documentation of future site-specific activities associated with new construction or modifications to existing facilities will be evaluated in light of the programmatic environmental analyses presented in this EIS and the potential effects of the proposed action. Application of the IAM serves to identify issues, impacts, areas of concern, and activities related to specific facilities or to future programmatic activities.

ATTACHMENT I

ACTIVITIES DEFINITION

(See Section 3 for detailed descriptions of activities.)

I. RESEARCH, DEVELOPMENT, TEST AND EVALUATION

A. Laboratory Work
1. Supplies in and out
2. Equipment Maintenance
3. Preparation of reagents and solutions

B. Storage of Chemicals. Biologicals, Supplies, and Radioisotopes
1. Supplies - plasticware, glassware
2. Chemicals - heavy metal salts, acids & bases, organics
3. Biologicals - replicating, nonlevels
4. Radioisotopes

C. Conduct Specific RDT&E Procedures

1. Logistics - remove, perform, decontaminate, dispose
2. Transportation - in, out, special requirements

D. Laboratory Animal Care and Use

E. Prototype Development of RDT&E Materials

1. Protective equipment and detectors
2. Biological materials for research and test

F. Testing
1. Humans
2. Equipment

II. ADMINISTRATIVE AND MANAGEMENT SUPPORT OF RDT&E ACTIVITIES

A. Operation and Maintenance
1. Utilities
2. Operations

B. Waste Stream Management
1. Air
2. Liquid
3. Solid

C. Planning and Design
1. Preparation of test methods for equipment
2. Preparation of test methods for biological and medical research
3. Design methods for medical protection
4. Design methods for physical protection

D. Program Management
   1. Primary sites
   2. Secondary sites
   3. Publication of Accomplishments and Results

APPENDIX K
PROGRAMMATIC ENVIRONMENTAL AND SOCIOECONOMIC ISSUES
TAKEN FROM THE BDRP FPEIS, SECTIONS 6.1 - 6.3

6. ENVIRONMENTAL AND SOCIOECONOMIC CONSEQUENCES

6.1 INTRODUCTION

The purpose of this section is to present the scientific and analytical basis for comparing the alternatives identified in section 4. Evaluation of reasonable alternatives for the BDRP, as discussed in section 4, revealed no unresolved conflicts concerning available resources, and identified no significant effects upon the quality of the human environment sufficient to warrant considering additional mitigation to supplement the elaborate controls and procedures that are already in place.

The BDRP has been an ongoing program for a number of years, and, as such, has been subject to continuous internal and external review processes to ensure that all BDRP activities are conducted in a manner that protects the health and safety of the workforce and the external environment Throughout this period of operation, the BDRP developed the present-day set of effective procedures, controls (section 3), and guidelines that mitigate impacts on the human environment. This section presents results of the analytical methodology (IAM, Appendix 6) used to identify relevant impacts and issues of the program. The rationale for identification of the alternatives considered to be reasonable, which include the preferred action (continue the BDRP and the no-action (terminate the BDRP) alternatives, is presented in section 4. Because the BDRP is ongoing, the actual impacts associated with the program are identified in section 5, Affected Environment. The discussion of environmental and socioeconomic consequences addresses these impacts as well as perceived impacts.

The following sub-sections describe the impacts of consequence and the relevant areas of concern resulting from the discrete elements of the BDRP as identified through application of the matrix analysis. Descriptions of the discrete elements of the BDRP primary sites, secondary sites, and programmatic categories, are presented in section 3. Program management is discussed in section 2.3. Primary sites are defined as DoD facilities having prime BDRP managerial responsibilities (sections 2.4 and 5.3). The secondary sites (sections 2.5. and 5.4 and Appendix 3) are other governmental laboratories and contractor facilities engaged in biological defense research activities. The total BDRP is managed (section 2.3.) from three primary sites: the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD; the U.S. Army Chemical Research, Development and Engineering Center, Edgewood Area, Aberdeen Proving Ground, MD; and U.S. Army Dugway Proving Ground, Dugway, UT.

Nine representative secondary sites were selected for detailed evaluation and analysis because the work performed at these sites involved organisms or toxins belonging to the three highest perceived risk/issue groups: high hazard organisms, toxins, or genetically engineered microorganisms (GEMs) (sections 3.5, 5.4 and Appendices 4 and 10). Within these three risk/issue groups, the selected sites were considered also to have the greatest potential for generating impacts. Thus, The Salk Institute - Government Services Division (TSI-GSD) at Swiftwater, PA, and Southern Research Institute (SoRI) at Birmingham, AL, conduct work on agents requiring BL-3 containment; Wright State University, Dayton, OR; Jefferson Medical College, Philadelphia, PA; and SRI, International' Menlo Park, CA, conduct BDRP work on toxins. The University of Massachusetts, Amherst, MA; New York State Department of Public Health Research Laboratories, Albany, NY; and Scripps Institute, LaJolla, CA, conduct BDRP studies categorized as genetic engineering. The Salk Institute, LaJolla, CA conducts studies of human hybridoma cells; this biotechnology was grouped with GEMs because many of the issues associated with this type of work are similar to those identified for work with GEMs.

The other secondary sites where BDRP work is performed were evaluated thoroughly, but in less detail. This was deemed appropriate because the in-depth evaluations, including site visits and interviews, served to verify the application of the programmatic tiering (based upon the IAM evaluations by risk/issue category) as a reasonable and reliable approach for impact analysis. The other BDRP secondary sites were evaluated individually on this basis utilizing available information 1) on the work involved, 2) the adequacy of facilities, 3) implementation of control measures, and 4) past performance history. Where appropriate, consultation was used to obtain needed information. The other secondary sites were also examined to determine if there were any unique circumstances that would affect the application of this approach. The results of this analysis confirmed that, in all cases, the potential impacts were either similar to, or of lesser consequence, than those examined at representative sites (see Appendix 3). Consideration was also given to any potential for cumulative or synergistic impacts. None were identified.

6.1.1 PROGRAMMATIC CATEGORIES- -

A more detailed discussion of these categories is presented in Appendix 4.

High Hazard Organisms: This category includes all program laboratory activities with organisms requiring biosafety levels 3 and 4 containment (See Appendices 11 and 12). Significant areas of concern associated with this activity include surface water, biological air quality, controversial issues, and the health of the workforce. When site-specific activities are considered, safety, regulatory and other controls adequately address the concerns for the biophysical environment and the risks of these organisms to public health and the environment become minor.

Benefits resulting from this category include maintenance of the national defense posture and contributions to scientific knowledge.

Low Hazard Organisms: This category includes simulants and low hazard Infectious agents requiring biosafety levels BL-1 and BL-2 containment (See Appendices 11 and 12). Reducing the need to use high hazard organisms through the use of simulants and less pathogenic organisms is considered to be a positive impact upon the health of the workforce. A significant benefit from this category of activity is the contribution to the national defense posture. There are no significant relevant areas of concern associated with this category.

Toxins: Inclusion of toxins in the BDRP may be perceived as a controversial issue. The potential for impacts upon surface water by activities in this category is considered a relevant area of concern, but controlled disposal methods prevent adverse impacts. Activities in this category contribute significantly to the national defense posture and to the scientific community.

Genetically Engineered Microorganisms (GEMs): The inclusion of genetic engineering methodology into the BDRP is critical to developing appropriate defense measures, and therefore makes a significant contribution to the national defense posture and, at the same time, to the scientific community. GEMs are the object of controversy within certain segments of the population, and the potential environmental impacts arising from their use have been addressed comprehensively by the NIH (See Appendix 10).

Rapid Diagnosis and Detection: The rapid diagnosis and detection research, development, and testing efforts are integral to maintaining the national defense posture. There are no relevant areas of concern perceived for this element of the BDRP

Vaccine and Drug Therapy Development : The development and testing of potential therapeutic drugs and Vaccines provide benefits to the global public health, to the scientific community, and make a significant contribution to the national defense posture as an integral part of the BDRP There is a minor concern associated with the use of medical research volunteer subjects, but, historically, this is a well-controlled activity and there have been no adverse impacts reported.

Other Program Research and Activities: Activities of this category include those subject areas of the program that do not appropriately fit into other defined categories and do not constitute discrete subject areas warranting separate consideration. These activities are integral to the overall contribution of the BDRP to national defense, but involve insignificant risks or potential for adverse impacts. There are no detrimental relevant areas of concern perceived for this element of the program.

6.1.2. PRIMARY SITES

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID): There are no significant environmental consequence associated with activities at USAMRIID. Controversial issues, national defense posture, and scientific benefit were identified as the three relevant areas of significant concern by the Impact Analysis Matrix (See Appendix 6). Since these areas relate to the program-wide issues, they are addressed in section 5.2.1, national environment. Surface water, biological air quality, labor force, public benefit and workforce were identified as relevant areas of minor concern. Due to the high hazard nature of many organisms studied at USAMRIID, potential risk to the surface water is perceived to be high, but is actually low when one examines the stringency of controls that are applied to effluents entering wastewater streams (See 5.2.2.1). The incorporation of special filters and air-handling capabilities into the laboratory complex ensures containment of, and safe operations with, these high hazard agents (See 5.2.2.1). The nature of research conducted at this institute may potentially present a minor concern for the health and safety of the workforce involved. However, personnel are protected by adherence to rigid safety protocols, application of specific laboratory procedures, use of biocontainment laboratories and equipment, and by immunization. Thus, safe conduct of this research in compliance with the standard operating procedures, guidelines, and controls will have no potentially significant consequences.

Effects of the labor force and public benefit were identified as two positive relevant areas of minor concern. The labor force at USAMRIID consists of approximately 570 people. This represents about 14% of all persons employed on Fort Detrick. Since most of the people who work at USAMRIID make their home in or near Frederick County, their employment, representing about 3.5% of the county's total payroll, has a significant positive effect on the local community (See 5.2.2.1). The positive impacts from the research activities performed at USAMRIID and their benefit to the public are discussed as part of the considerations for the national environment in section 5.2.1.

U.S. Army Chemical Research, Development and Engineering Center (CRDEC): The examination of CRDEC's activities under the BDRP revealed no significant environmental consequences. National defense posture was identified as a positive relevant area of significant concern (See Appendix 6), and is discussed as one of the national environment considerations in section 5.2.1. Effects of the labor force were identified as a positive relevant area of minor concern. The employment of 19 persons, many part-time, at CRDEC under BDRP funding represents about 1.3% of the total CRDEC employees, and about 0.075% of the regional personal income (See 5.2.2.2). Thus, the economic impact of the labor force associated with the BDRP at this facility is very small.

U.S. Army Dugway Proving Ground (DPG): The examination of DPG's activities under the BDRP revealed no significant environmental consequences. Controversial issues and national defense posture were identified as relevant areas of significant concern, and are discussed as part of the national environment considerations in section 5.2.1. Labor force was identified as a positive relevant area of minor concern. The employment of 10 persons under the funding of the BDRP represents about 0.7% of the total DPG personnel, and about 0.1% of the regional personal income (See 5.2.2.3). Thus, the economic impact of the labor force associated with the BDRP at this facility is small.

6.1.3 SECONDARY SITES

Nine representative BDRP secondary sites were selected *for* in-depth analysis. IAM evaluation concentrated on the portion of the work performed under the BDRP sponsorship at each site. Consideration was given to any aspects of the site, or other ongoing activities, which would influence the potential for any BDRP related impacts to become significant as a result of cumulative or synergistic effects. A list of all secondary sites is provided in Appendix 3. Eight of the nine secondary sites - examined, utilizing the IAMs, indicated no relevant areas of - significant concern (See Appendix 6). The IAM for the Salk Institute, Government Services Division, identified national defense posture as a positive relevant area of significant concern. This is discussed as part of the national environment in section 5.2.1.

Nine relevant areas of minor concern were identified for one or more of the secondary sites (See Appendix 6). These are: surface water, ambient air quality, biological air quality, labor force, controversial issues, national defense posture, scientific benefit, public benefit and workforce.

Surface water and biological air quality were identified as relevant areas of minor concern at the Salk Institute, Government Services Division, and the Southern Research Institute (SoRI). Research at both of these institutions is conducted with organisms requiring BL-3 containment facilities, thus providing a potential for minor impacts. However, due to the control measures and safety features inherent in the structural and operational characteristics of these facilities (See 5.2.3.1), the potential for environmental consequences on surface water and biological air quality becomes insignificant. Ambient air quality was identified to be a potentially relevant area of minor concern at the Salk Institute, Swiftwater, PA. This is attributed to the disposal of test animals and their wastes by autoclaving, followed by incineration of these wastes. However, these procedures are performed in compliance with the requirements of a state permit, which minimizes the potential for

any consequences to the environment. A potential minor impact on the health of the workforce was identified at both the Salk Institute, Government Services Division, and at the Jefferson Medical College. A safety committee at both of these facilities manages general laboratory safety hazards and requires laboratory personnel to follow specific guidelines that cover recurring activities in the operation of the laboratory (see 5.2.3.1 and 5.2.3.3). The laboratory personnel who may come in contact with high hazard organisms or toxins used in research are immunized for their maximum protection.

Economic effect of the labor force was identified as a positive relevant area of minor concern for the Salk Institute, Government Services Division. The employment of approximately 55 persons under the BDRP sponsorship at this institute represents 0.23% of the regional personal income (see 5.2.3.1). Thus, the economic impact of the labor force associated with the BDRP in the region of this facility is positive, but minor. National defense posture, scientific benefit, and public benefit were identified as relevant areas of minor concern by the IAMs for several secondary sites. These benefits are discussed as site-national considerations in section 5.2.1. Controversial issues related to GEMs were identified as a relevant area of minor concern for the Wadsworth Center for Laboratories and Research, New York State Department of Public Health. These issues are discussed as part of the national environment considerations in section 5.2.1.

The remainder of the secondary sites were analyzed on the basis of their respective risk/issue categories. Appropriate checks were made to assure that the facilities were adequate for the ongoing research or testing activities. In addition, an examination of the control measures and environmental compliance requirements was conducted to verify that appropriate measures were in place to protect the workforce and the external environment. Additional safety policies relevant to secondary sites were initiated after the publication of the DEIS and are described in Section 3.3.2. The potential for cumulative effects was also examined. The overall analysis of all secondary sites indicated no significant adverse impacts on the human environment, either on an individual basis, or cumulatively.

6.1.4 SITES OUTSIDE THE UNITED STATES

The BDRP sites located outside the United States are also included in Appendix 3. Requirements for NEPA evaluation of sites abroad are discussed in Section 5.2. No potential was found to significantly harm any aspect of the environment of any other country; thus no further examination of international participants in the BDRP was conducted.

6.2 SUMMARY OF IMPACTS

In summary, analyses of individual and cumulative effects of the BDRP revealed the beneficial effects of the program are: maintenance of the national defense posture, contributions to scientific knowledge, and benefits to the global population by development of vaccines and drugs for naturally occurring animal and human diseases.

Relevant areas of concern are associated with the potential for impacts on: surface water, air quality, human health of the workforce and contiguous populations, economic impacts of the BDRP expenditures, social concerns, safety during construction phases, and controversial issues. With regulatory and other controls in place, risks to the environment and workforce become minor. All other environmental and socioeconomic impacts were determined to be insignificant or non-existent. No significant cumulative or synergistic adverse impacts were identified.

The program activities identified as most responsible for the potential impacts were: program management, planning and designing the research, the development and testing program, and the actual procedures required for research, development, and testing. In all cases, the potential for impacts was found to be based upon perceptions that were not supported by actual data or experiences.

Analysis of the BDRP identified no conflicts in alternative uses of resources, or land-use plans or policies. In addition, there were no short-term uses of the environment that materially affected the maintenance and enhancement of long-term productivity. No BDRP activities produced adverse impacts on the natural ecosystem balance at any location, either from the programmatic or site-specific perspectives. The program utilizes depletable, non-renewable energy resources, such as natural gas, coal, and fuel oil, but the quantities cons-timed are small and result in insignificant impacts. Use of financial and energy resources are the only areas where measurable commitments, though minor, of irreversible or irretrievable uses of resources were identified. There were no activities identified as producing adverse or significant impacts on cultural or natural resources, such as historic or archaeological sites, unique geographical areas, or ecosystems. The BDRP is an ongoing, in place, research program that will have no effect on cultural resources. All current BDRP experimentation takes place in established research laboratories. Future BDRP construction projects that may affect cultural resource sites will be addressed under separate NEPA documentation when such projects are proposed. No endangered species or designated critical habitat would be affected.

6.3 CONSEQUENCES OF THE ALTERNATIVES CONSIDERED

The identification of alternatives considered and the basis for eliminating non-relevant alternatives are discussed in section 4.

6.3.1 ALTERNATIVE TO CONTINUE THE BDRP

The preferred alternative is continuation of the BDRP. Under this alternative, the benefits and contributions that the BDRP makes to the national defense posture, scientific knowledge, and to the global public health would continue. Controversy over the development of defensive measures for biological warfare threats and the use of genetic engineering methodologies in the program will also continue with this alternative.

In addition to the controversial issues, there is a perception by segments of the population that events external to the controls of the program, such as a catastrophic accident or an act-of-nature, may cause a serious outbreak of an uncontrollable disease. The types of acts-of-nature or catastrophic incidents proposed include seismic or climatic disturbances, fire, explosions, falling meteorites, airplane crashes, terrorism, riots, and sabotage. The potential for release of contaminated test materials or infectious organisms outside of the laboratory through any number of means, such as escape of infected animals, accidental spills of infectious organisms, contagious laboratory workers, uncontrolled vectors, uncontrolled open-air testing, and purposeful direct releases to the environment, are perceived by certain segments of the population as a constant threat or risk. This aura of concern about events which have never occurred will no doubt persist if the BDRP is continued.

The potential consequences associated with extraordinary catastrophic, unpredictable events, should they occur, are evaluated in Appendix 9. Although occurrence of an extraordinary event is theoretically possible, the probability of such an occurrence at any given time is considered to be remote. The opportunity for an infectious disease to spread uncontrollably as a result of an extraordinary event has been evaluated and found to be immeasurably small (see Appendix 8). Considering the maximum quantity of infectious disease organisms or toxins contained at any one of the BDRP locations, the worst credible event that could result from the above mentioned catastrophes would create a potentially infectious or hazardous environment only within a few meters of the origin, and the duration of the hazard would be on the order of minutes to hours. Considering the nature of the organisms used, if any humans or animals should become infected as a result of such an incident, it would be highly unlikely that a disease would spread from man to man, animal to animal, or animal to man, because these routes are not the normal mode of transmission of these organisms (see Appendices 7 and 9). The majority of humans or animals initially infected could be treated effectively, and even without treatment, a disease would probably spread no farther than the initially infected contacts. The type of catastrophic event discussed here pertains to all real life endeavors without regard to location or time, and are beyond the reasonable control of the BDRP or any other agency. Within the DoD, the capability exists to respond effectively to any of the aforementioned incidents. However, because of the highly speculative and improbable nature of such events occurring, it is not believed to be necessary to modify or terminate the BDRP in order to eliminate the potential occurrence of these remote and unlikely events, which must then be followed by other, equally unlikely, events in order to cause even localized adverse consequences.

Within the BDRP as in virtually any endeavor in the biological sciences, there is the unavoidable potential for injuries or infections resulting from accidents in any phase of the program. Since the inception of the BDRP there have been no fatalities or untreatable injuries for any reason associated with the BDRP (see Appendix 8). Accidents which have occurred in the past include needle sticks, laboratory spills, equipment breakage, punctures from broken laboratory ware and animal bones, animal bites, and cuts during necropsy procedures. In all cases, appropriate monitoring and treatment were provided to affected personnel, and no overt disease has ever developed in either close personal contacts of the laboratory worker or in the community. It is anticipated that, regardless of the level of preventive efforts and controls, these types of accidents will inevitably continue at a low frequency. The overall safety record of the BDRP has been exemplary; with the special attention devoted to occupational and biosafety, the safe conduct of the program is expected to continue.

6.3.2 ALTERNATIVE TO TERMINATE THE BDRP

Termination of the program (no action alternative) would eliminate the perceived and potential impacts of the BDRP on the workforce, the general population, and the biophysical environment. The actual minor adverse impacts would also cease. It has been determined that none of these significantly affect the quality of the human environment. Objections to the study of potential biological warfare agents and development of defensive measures against them would be eliminated, but the objections of special interest groups and individuals to the existence and use of genetic engineering as a biomedical technology would continue. The genetic engineering efforts in the BDRP represent a very minute portion of the usages of genetic engineering by the total biomedical research and development community on a national or worldwide scale. Termination of the program would forfeit the program benefits of maintaining the national defense posture, contributions to the scientific community, and to the global population. The positive economic impacts of the workforce on local economies would be lost as well. While not of a major national consequence, these types of impacts are significant locally.

6.4 MITIGATION AND MONITORING

Mitigation of potential adverse impacts resulting from normal operational activities such as biocontainment, waste discharge and disposal, and accidents is accomplished by the implementation of operational, safety, security, and regulatory controls (Section 3.3) which are established based upon federal, state, and institutional criteria. Because of the nature of the BDRP there will always exist an element of risk. Appropriate concern for the inherent risks is properly expressed through the implementation of adequate measures to protect the workforce and the environment. Continuous monitoring and surveillance of all phases of the BDRP by each institution and by appropriate Federal and state authorities have effectively eliminated significant adverse impacts to the biophysical environment and to human health. The controls in effect throughout every aspect of the BDRP are adequate, and implementation of more stringent monitoring, or development of new criteria to provide, in theory, further protection for the workforce or the external environment, are not considered to be necessary.

APPENDIX L
PROGRAM MATRIX ANALYSIS SUMMARY
TAKEN FROM THE BDRP FPEIS, APPENDIX 6

Refer to Appendix 4 for detailed information on each programmatic risk/issue category.

PROGRAM MATRIX ANALYSIS SUMMARY

Category: High Hazard Organisms

Matrix analysis of this program category concluded that the use of high hazard organisms in the BDRP brings with it concerns in the areas of surface water, biological air quality, economic activity, controversy, social concerns, health risks to the workforce and the general population, as well as special facility requirements for safe conduct of the work. When site-specific activities are considered, regulatory and other controls adequately address these issues and concerns. Thus, the risks of working with these organisms to human health and to the environment become minor.

High hazard infectious organisms are of major concern as potential national defense threats. The public benefits of the program are potentially, significant contributions to the scientific community and to the nation's well-being.

The activities of storage, prototype development, testing, operation and maintenance, and waste stream management were not germane to the analysis of this program category. Prototype development and testing are relevant to the drug and vaccine development category, and are discussed separately. Operation and maintenance and waste stream management activities were evaluated in the site-specific analyses of primary and secondary sites.

There is a potential for low level impact to the surface water from high hazard infectious organisms. The potential impacts are mitigated by controls under normal operations. Activities that could produce potential impacts are laboratory work and procedures. Thus, surface water has been identified as a relevant area of significant concern because of the perceived high risk by certain segments of the public. Biological air quality has also been identified as a relevant area of significant concern for the same reason as discussed above for water quality.

The BDRP has a low positive impact on the economic activity, which is due to the purchase of laboratory supplies and equipment from the local community. Due to the nature of research conducted at each site, the impact on economic activity varies depending on the site. Research involving high hazard infectious organisms is perceived to be of high risk and controversial in nature, thus it is indicated to be a relevant area of significant concern. However, studies of high hazard organisms are conducted in BL-3 and BL-4 laboratory containment facilities (Appendix 12), and in compliance with the CDC-NIH guidelines on biosafety (Appendices 5 and 12), therefore providing protection to the laboratory workers and to the general population. Social concerns are related to the perceived highly controversial nature of this research.

National defense posture, scientific benefit, and public benefit are discussed as part of the considerations of the national environment {section 5.2). There is a low but acceptable inherent risk to the workforce in working with the high hazard infectious organisms. (including receiving special immunization with vaccines that are used to protect personnel at risk), that is minimized by safety procedures, equipment, and practices. Thus, impacts on the workforce have been identified as a relevant area of significant concern. A low level potential impact on the general population was identified from the procedures activity. However, with the appropriate controls and safeguards in place, the actual impacts are identified as a relevant area of minor concern.

Construction was assigned a low impact rating for laboratory work and procedures activities due to the special containment facilities that are required for work with high hazard infectious organisms. Potential accidents could involve exposure of an individual to a high hazard infectious organism. Although there is a potential for accidents in the laboratory, the probability of their occurrence is low with the appropriate controls in place (Appendices 11 and 12).

IAM (Fig A6-13) Summary

Significant Relevant Areas of Concern:

Water -	Surface
Air Quality-	Biological
Public Opinion-	Controversial Issues
Program Benefits-	National Defense Posture (+)
Human Health-	Workforce
Safety-	Construction

Minor Relevant Areas of Concern:

Program Benefits-	Scientific Benefit
	Public Benefit
Human Health -	General Population

All other areas were determined to have insignificant environmental impacts.

PROGRAM CATEGORY: High Hazard Infectious Organisms

LEGEND
H=HIGH
L=LOW
+=POSITIVE

CONTROLS	LABORATORY WORK	* STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
	ACTIVITIES: RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT			
OPERATIONAL	✓		✓	✓						
SAFETY	✓		✓	✓						
SECURITY				✓						
REGULATORY	✓		✓	✓					✓	✓

*Activities not applicable

RISKS	LABORATORY WORK	* STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED	H		H	L					—	—
ACTUAL	L		L	L					—	—

	POTENTIAL AREAS IMPACTED	LABORATORY WORK	* STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	RELEVANT AREAS OF CONCERN S	M
BIOPHYSICAL	1. LAND USE:														
	Agriculture														
	Industrial														
	Commercial														
	Residential														
	Recreation														
	Wetlands														
	Floodplains														
	Unique Geographical Area														
	Policies														
	2. PLANT AND ANIMAL ECOLOGY:														
	Population														
	Terrestrial Habitats														
	Aquatic Habitats														
	Endangered Species														
	3. GEOLOGY:														
	Soils														
	Topography														
	Erosion														
	4. WATER:	L		L								L	H	✓	
	Surface														
	Ground														
	5. AIR QUALITY:														
	Ambient Standards														
	Biological	L		L								L	[illegible]	✓	
	6. AGRICULTURE:														
	Crops														
	Forestry														
	7. CULTURAL RESOURCES:														
	Historical														
	Archeological														
	8. ENERGY RESOURCES:														
	Renewable Supplies														
	Nonrenewable														
SOCIOECONOMIC	9. SOCIOLOGICAL ENVIRONMENT:														
	Demographics														
	Aesthetics														
	Noise														
	Odors														
	10. ECONOMIC ENVIRONMENT:														
	Labor Force														
	Economic Activity	L+		L+											
	Property Values														
	11. PUBLIC OPINION:	L		H	L					H	H			✓	
	Controversial Issues										L				
	Local Concerns														
	12. PROGRAM BENEFITS:	H+		H+	L+					H+	H+	H+	—	✓	
	National Defense Posture	H+		H+						L+		L+	—		✓
	Scientific Benefit	L+		L+											✓
	Public Benefit														
	13. TRANSPORTATION:														
	Road														
	Rail														
	Air														
	Pipeline														
	14. HUMAN HEALTH:	L		L	L							L	L	✓	
	Workforce			L								L	—		✓
	General Population														
	15. SAFETY:	L		L										✓	
	Transportation														
	Occupational														
	Accidents	L		L											

	LABORATORY WORK	* STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
SIGNIFICANT	—		✓	—					✓	✓
MINOR	✓		—	—					—	—

Figure A6-13

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PROGRAM MATRIX ANALYSIS SUMMARY

Category: Low Hazard Organisms

Simulants and low hazard organisms are integral to the BDRP, not because they are considered to be potential threats but because working with low hazard organisms poses significantly less risk to the workforce. The proportionately greater ease of working under BL1-2 vs BL3-4 conditions enables a much greater productivity in relation to the man-hours and materials expended and laboratory space occupied. Thus, the use of simulants and Low hazard organisms, where applicable, is considered to be a positive minor area of concern for the workforce and to the national defense posture.

The activities of storage, prototype development, operation and maintenance, waste stream management, or planning and design do not apply to this program category. Testing was found to be applicable because open-air testing with simulants, while not conducted on a routine basis, remains an integral part of the program. Surface water, ambient air quality, economic environment, public opinion, program benefits, and human health were assigned a low level of impact for applicable activities.

There would be no impact to surface water from the simulants used in open-air testing because simulant organisms occur naturally throughout the environment. However, a low rating was assigned because of the perception of impacts by certain segments of the public. There is a minor impact on ambient air quality from vehicular traffic during open-air testing. The BDRP has a low positive impact on the economic activity due to money brought into the economy from purchasing laboratory equipment and supplies. There is a perception of risk associated with open-air testing among certain segments of the public. Thus, a low impact was assigned to controversial issues. This is not considered a relevant area of concern.

National defense posture and scientific benefits are discussed as part of the considerations of the national environment (section 5.2). There is a low positive benefit to the workforce because low hazard organisms and simulants pose less risk to the health of the workforce than do the high hazard organisms, thereby minimizing the potential for adverse impacts. Thus, impacts on the workforce have been identified as positive relevant area of minor concern.

IAM (Fig A6-14) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Program Benefits-	National Defense Posture (+)
Human Health-	Workforce (+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Low Hazard Organisms

ACTIVITIES (RESEARCH DEVELOPMENT TESTING AND EVALUATION | ADMINISTRATION AND MANAGEMENT)

CONTROLS	LABORATORY WORK	*STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	*PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	*PLANNING AND DESIGN	PROGRAM MANAGEMENT
OPERATIONAL	✓		✓	✓		✓				
SAFETY	✓		✓	✓		✓				
SECURITY				✓		✓				
REGULATORY				✓		✓				✓

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS	LABORATORY WORK	*STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	*PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	*PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED	—		—	—		L				—
ACTUAL	—		—	—		—				—

RELEVANT AREAS OF CONCERN

POTENTIAL AREAS IMPACTED	LABORATORY WORK	*STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	*PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	*PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
BIOPHYSICAL														
1. LAND USE: Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Utilities														
2. PLANT AND ANIMAL ECOLOGY: Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY: Soils														
Topography														
Erosion														
4. WATER: Surface						L								
Ground														
5. AIR QUALITY: Ambient Standards						L								
Biological														
6. AGRICULTURE: Crops														
Forestry														
7. CULTURAL RESOURCES: Historical														
Archaeological														
8. ENERGY RESOURCES: Replaceable Supplies														
Non-Replaceable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT: Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT: Labor Force														
Economic Activity														
Property Values														
11. PUBLIC OPINION: Controversial Issues						L								
Special Concerns														
12. PROGRAM BENEFITS: National Defense Posture	L+		L+			L+				L+				✓
Scientific Benefit										+				
Public Benefit														
13. TRANSPORTATION: Road														
Rail														
Air														
Marine														
14. HUMAN HEALTH: Workforce	L+		L+											✓
General Population														
15. SAFETY: Transportation														
Occupational														
Accidents														
SIGNIFICANT	—		—	—		—				—				
MINOR	—		—	—		✓				—				

Figure A6-14

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PROGRAM MATRIX ANALYSIS SUMMARY

Category: Toxins

Studies on toxins are integral to the BDRP contribution to the national defense posture and contribute to the scientific community at large. Inclusion of toxins in the BDRP may be a controversial issue. Regulated disposal methods are necessary to prevent potential adverse impacts on surface water.

The activities involving storage, prototype development, testing, operation and maintenance, and waste stream management do not apply to this program category. Surface water, economic environment, public opinion, program benefits, human health, and safety were identified as impacted by applicable activities as discussed below.

There is a potential for low level impact to surface water from toxins. Although the potential impacts are dependent on the varying degrees of toxicity, they are mitigated by controls under normal operations. Activities with potential for impact are laboratory work and procedures. Surface water has been identified as a relevant area of minor concern because of the perceived risk by certain segments of the public. The BDRP has a low positive impact on the economic activity due to the money brought into the economy from purchase of laboratory supplies and equipment. The public controversy relates to the overall BDRP and whether toxin research should be a legitimate element of the defensive program. Thus, public controversy is considered a relevant area of minor concern.

The development of vaccines and therapeutic drugs for potential biological warfare threat toxins enhances the national defense posture. Additional program benefits are discussed as part of the considerations of the national environment (section 5.2). There is a low but acceptable inherent risk to the workforce in working with the toxins. These risks are minimized by the use of special biosafety facilities, equipment, and procedures for those activities that would otherwise cause a high potential for exposure. Basic research activities with toxins use extremely small quantities at any one time, which also minimizes the potential risk to the health of laboratory workers. Potential accidents could involve exposure of an individual to a toxin; however, the probability of this occurring is very low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-15) Summary

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Water- Surface

Public Opinion- Controversial Issues

Program Benefits- Scientific Benefit (+)

All other areas were determined to have insignificant environmental impacts.

PROGRAM CATEGORY: Toxins

ACTIVITIES: RESEARCH DEVELOPMENT TESTING AND EVALUATION (Laboratory Work, * Storage, Procedures, Laboratory Animal Care, * Prototype Development, * Testing); ADMINISTRATION AND MANAGEMENT (* Operation and Maintenance, * Waste Stream Management, Planning and Design, Program Management)

LEGEND
H=HIGH
L=LOW
+=POSITIVE

CONTROLS	Laboratory Work	* Storage	Procedures	Laboratory Animal Care	* Prototype Development	* Testing	* Operation and Maintenance	* Waste Stream Management	Planning and Design	Program Management
OPERATIONAL	✓		✓	✓						
SAFETY	✓		✓	✓						
SECURITY				✓						
REGULATORY	✓		✓	✓					✓	✓

*Activities not applicable

RISKS	Laboratory Work	* Storage	Procedures	Laboratory Animal Care	* Prototype Development	* Testing	* Operation and Maintenance	* Waste Stream Management	Planning and Design	Program Management
PERCEIVED	L		L	—					—	—
ACTUAL	L		L	—					—	—

POTENTIAL AREAS IMPACTED	Laboratory Work	* Storage	Procedures	Laboratory Animal Care	* Prototype Development	* Testing	* Operation and Maintenance	* Waste Stream Management	Planning and Design	Program Management	A	P	RELEVANT AREAS OF CONCERN S	M
BIOPHYSICAL														
1. LAND USE: Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY: Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY: Soils														
Topography														
Erosion														
4. WATER: Surface	L		L								L			✓
Ground														
5. AIR QUALITY: Ambient Standards														
Biological														
6. AGRICULTURE: Crops														
Livestock														
7. CULTURAL RESOURCES: Historical														
Archeological														
8. ENERGY RESOURCES: Renewable Supplies														
Non-renewable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT: Demographics														
Aesthetics														
Noise														
[illegible]														
10. ECONOMIC ENVIRONMENT: Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION: Controversial Issues			L						L	L				✓
Social Concerns														
12. PROGRAM BENEFITS: National Defense Posture	H+		H+	L+					H+	H+			✓+	
Scientific Benefit	L+		L+						L+	L+				✓+
Public Benefit														
13. TRANSPORTATION: Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH: Workforce	L		L											
General Population														
15. SAFETY: Construction														
Operations														
Accidents	L		L	L										
SIGNIFICANT	—		✓	—					—	—				
MINOR	✓		—	—					✓	✓				

Figure A6-15

PROGRAM MATRIX ANALYSIS SUMMARY

Category: Genetically Engineered Microorganisms

Genetically engineered microorganisms (GEMs) were included for separate analysis, not because they were perceived to be a significant risk, but because GEMs have been the object of controversy within certain segments of the population. Nevertheless, the controversial issue notwithstanding, genetic engineering is an integral part of any viable biomedical research program. The inclusion of genetic engineering methodology in the BDRP is critical to developing effective defense measures.

The activities of storage, laboratory animal care, prototype development, testing, operation and maintenance, waste stream management, and planning and design do not apply to this category. Economic environment, public opinion, and program benefits, were impacted by applicable activities and are discussed below.

There are low level positive impacts to the economic activity associated with the laboratory work and procedures. Research involving use of r DNA molecules in the construction of genetically engineered microorganisms is perceived to be controversial in nature. However, this controversy is not related to specific sites, but to the overall BDRP (refer to section 5.2 on the national environment considerations). Social concerns are related to the perceived controversial nature of this research. National defense posture, scientific benefit, and public benefit are also discussed as part of the considerations of the national environment.

IAM (Fig A6-l6) Summary-

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Public Opinion- Controversial Issues

Program Benefits- Scientific Benefit (+)

All other areas were determined to have insignificant environmental concerns.

PROGRAM CATEGORY: Genetically Engineered Microorganisms

ACTIVITIES

LEGEND
H=HIGH
L=LOW
+=POSITIVE

CONTROLS	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	* PLANNING AND DESIGN	PROGRAM MANAGEMENT
	RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT			
OPERATIONAL	✓		✓							
SAFETY	✓		✓							
SECURITY										
REGULATORY	✓		✓							✓

*Activities not applicable

RISKS	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	* PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED	L		L							L
ACTUAL	—		—							—

POTENTIAL AREAS IMPACTED	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	* PROTOTYPE DEVELOPMENT	* TESTING	* OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	* PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	RELEVANT AREAS OF CONCERN: S	RELEVANT AREAS OF CONCERN: M
BIOPHYSICAL														
1. LAND USE: Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY: Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY: Soils														
Topography														
Erosion														
4. WATER: Surface														
Ground														
5. AIR QUALITY: Ambient Standards														
Biological														
6. AGRICULTURE: Crops														
Livestock														
7. CULTURAL RESOURCES: Historical														
Archeological														
8. ENERGY RESOURCES: Renewable Supplies														
Nonrenewable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT: Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT: Labor Force														
Economic Activity	L+		-											
Property Values														
11. PUBLIC OPINION: Controversial Issues			H							H				✓
Social Concerns			L											
12. PROGRAM BENEFITS: National Defense Posture	L+		H+							H+			✓+	
Scientific Benefit			H+							L+				ø
Public Benefit			L+											
13. TRANSPORTATION: Road														
Rail														
Air														
Water														
14. HUMAN HEALTH: Workforce														
General Population														
15. SAFETY: Construction														
Operational														
Accidents														
SIGNIFICANT	—		✓							—				
MINOR	—		—							✓				

Figure A6-16

PROGRAM MATRIX ANALYSIS SUMMARY

Category: Rapid Diagnosis and Detection

While the rapid diagnosis and detection portion of the BDRP is an important component of the defensive effort, no relevant areas of concern were perceived for this element of the program. Where development of reagents for testing of products and/or equipment would involve higher levels of risk, such as use of infectious organisms or toxins, the analysis of environmental impact for this subject area was considered under those appropriate categories.

The activities of storage, laboratory animal care, testing, operation and maintenance, and waste stream management do not apply to this program category. Economic environment and program benefits were impacted by applicable activities. The development of prototypes of assay systems, detection methodologies based on potential biological materials, and remote sensor detection equipment have a positive low level impact on the local community associated with these activities. The development of rapid identification and diagnosis methodologies for potential biological warfare threat agents enhances the national defense posture with respect to these threats. The BDRP scientists have shared their expertise, methodologies, and reagents with health scientists in other countries where outbreaks of diseases such as Rift Valley fever have occurred, thus contributing to the overall scientific benefit.

IAM (Fig A6 - 17) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

All other areas were determined to have insignificant environmental concerns.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Rapid Diagnosis and Detection

LEGEND
H=HIGH
L=LOW
+=POSITIVE

ACTIVITIES	Research Development Testing and Evaluation: Laboratory Work	* Storage	Procedures	* Laboratory Animal Care	Prototype Development	* Testing	Administration and Management: * Operation and Maintenance	* Waste Stream Management	Planning and Design	Program Management
CONTROLS: OPERATIONAL	✓		✓		✓				✓	✓
SAFETY										
SECURITY										
REGULATORY			✓		✓				✓	✓

*Activities not applicable

RISKS	Laboratory Work	* Storage	Procedures	* Laboratory Animal Care	Prototype Development	* Testing	* Operation and Maintenance	* Waste Stream Management	Planning and Design	Program Management
PERCEIVED	—		—		—				—	—
ACTUAL	—		—		—				—	—

POTENTIAL AREAS IMPACTED	Laboratory Work	* Storage	Procedures	* Laboratory Animal Care	Prototype Development	* Testing	* Operation and Maintenance	* Waste Stream Management	Planning and Design	Program Management	A	P	RELEVANT AREAS OF CONCERN: S	M
BIOPHYSICAL														
1. LAND USE: Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY: Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY: Soils														
Topography														
Erosion														
4. WATER: Surface														
Ground														
5. AIR QUALITY: Ambient Standards														
Biological														
6. AGRICULTURE: Crops														
Livestock														
7. CULTURAL RESOURCES: Historical														
Archeological														
8. ENERGY RESOURCES: Renewable Supplies														
Non-Renewable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT: Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT: Labor Force														
Economic Activity	L+		L+		L+									
Property Values														
11. PUBLIC OPINION: Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS: National Defense Posture	L+		L+		L+				L+	L+				✓
Scientific Benefit	L+		L+											
Public Benefit														
13. TRANSPORTATION: Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH: Workforce														
General Population														
15. SAFETY: Construction														
Operational														
Accidents														
SIGNIFICANT	—		—		—				—	—				
MINOR	—		—		—				—	—				

Figure A6-17

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PROGRAM MATRIX ANALYSIS SUMMARY

Category: Vaccine and Drug Therapy Development

The program category of "vaccine and drug therapy development" applies only to the preclinical and clinical testing of these medical items. Other research and developmental aspects of this topic are covered under one or more of the other "risk" categories. For this reason, laboratory work, procedures, operation and maintenance, and waste stream management were considered to be not applicable to this impact analysis. The preclinical animal challenge efficacy studies, which may involve use of infectious organisms or toxins, were also considered under those risk categories and were not considered under this impact analysis. The controversial aspect of vaccine and drug development relates to the use of laboratory animals.

In addition, Phase III clinical testing of drugs, biologics or vaccines is conducted only where and when natural disease occurs. In such cases, tests are conducted under appropriate controlled conditions meeting the human testing standards of the United States and the country in which the study may be conducted. Under test conditions, no introduction of an organism into the environment occurs, and no additional risk to human health and safety occurs beyond that which results from the natural disease.

The development and testing of these drugs and vaccines have proven benefits to public health and to the scientific community, in addition to significantly contributing to the national defense posture as an integral part of the BDRP. Vaccines developed by the BDRP have been used to fight outbreaks of disease such as the Rift Valley Fever outbreak in central Africa and VEE epidemic in south Texas.

As with testing of any new drug or vaccine, there is a small, but identifiable, risk to the medical research volunteer subject (MRVS) who participates in phase I and II clinical trials. Thus, impacts on the general population (MRVS) have been identified as a relevant area of minor concern.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Vaccine and Drug Therapy Development

LEGEND
H=HIGH
L=LOW
+=POSITIVE

CONTROLS	*LABORATORY WORK	STORAGE	*PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
	ACTIVITIES: RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT			
OPERATIONAL		✓		✓	✓	✓				
SAFETY		✓		✓	✓	✓				
SECURITY		✓		✓	✓	✓				
REGULATORY		✓		✓	✓	✓			✓	✓

*Activities not applicable

RISKS	*LABORATORY WORK	STORAGE	*PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED		—		—	—	L			—	—
ACTUAL		—		—	—	L			—	—

POTENTIAL AREAS IMPACTED	*LABORATORY WORK	STORAGE	*PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	RELEVANT AREAS OF CONCERN S	M
BIOPHYSICAL														
1. LAND USE: Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY: Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY: Soils														
Topography														
Erosion														
4. WATER: Surface														
Ground														
5. AIR QUALITY: Ambient Standards														
Biological														
6. AGRICULTURE: Crops														
Livestock														
7. CULTURAL RESOURCES: Historical														
Archeological														
8. ENERGY RESOURCES: Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT: Demographics														
Aesthetics														
Noise														
[illegible]														
10. ECONOMIC ENVIRONMENT: Labor Force														
Economic Activity														
Property Values														
11. PUBLIC OPINION: Controversial Issues				L										
Social Concerns														
12. PROGRAM BENEFITS: National Defense Posture		L+		L+	L+	H+			L+	L+			✓	
Scientific Benefit		L+			L+	L+			L+	L+				✓
Public Benefit					L+	L+								✓
13. TRANSPORTATION: Road														
Rail														
Air														
[illegible]														
14. HUMAN HEALTH: Workforce														
General Population **						L					L	L		✓
15. SAFETY: Construction														
Occupational														
Accidents														

**Refers To Medical Research Volunteer Subjects (MRVS)

	*LABORATORY WORK	STORAGE	*PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	*OPERATION AND MAINTENANCE	*WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
SIGNIFICANT		—		—	—	—			—	—
MINOR		—		—	✓	✓			—	—

Figure A6-18

IAM (Fig A6-18) Summary

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Program Benefits- Scientific Benefit (+)
Public Benefit (+)

Human Health- General Population (MRVS)

All other areas were determined to have insignificant environmental concerns.

PROGRAM MATRIX ANALYSIS SUMMARY

Category: Other Program Research and Activities:

This category includes those subject areas of the program that do not appropriately fit into one or more of the categories defined, that are likely to have imperceptible, if any, impact on the human or natural environment, and.were not discrete subject areas warranting separate consideration. Examples of these types of activities are literature studies, purification of immune plasm, and handling of non-hazardous biological laboratory materials. This category does not involve activities concerning storage, laboratory animal care, testing, operation and maintenance, and waste stream management. These activities were evaluated in relation to this program area under site-specific evaluations.

While portions of this category are inherent to the overall contribution of this BDRP to national defense, no detrimental relevant areas of concern were perceived in this element of the program.

IAM (Fig A6-19) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Program Benefit- National Defense Posture (+)

All other areas were determined to have insignificant environmental concerns.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Other Program Research and Activities

	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	* TESTING	OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
ACTIVITIES	RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT			
CONTROLS: OPERATIONAL	✓		✓		✓				✓	✓
SAFETY										
SECURITY										
REGULATORY			✓		✓				✓	✓

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	* TESTING	OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED	—		—		—				—	—
ACTUAL	—		—		—				—	—

POTENTIAL AREAS IMPACTED	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	* TESTING	OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	RISKS A	RISKS P	RELEVANT AREAS OF CONCERN S	RELEVANT AREAS OF CONCERN M
BIOPHYSICAL														
1. LAND USE: Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY: Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY: Soils														
Topography														
Erosion														
4. WATER: Surface														
Ground														
5. AIR QUALITY: Ambient Standards														
Biological														
6. AGRICULTURE: Crops														
Livestock														
7. CULTURAL RESOURCES: Historical														
Archeological														
8. ENERGY RESOURCES: Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT: Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT: Labor Force														
Economic Activity	L+		L-		L+									
Property Values														
11. PUBLIC OPINION: Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS: National Defense Posture	L+		L+		L+				L+	L+				L+
Scientific Benefit	L+		L+											
Public Benefit														
13. TRANSPORTATION: Road														
Rail														
Air														
Water														
14. HUMAN HEALTH: Workforce														
General Population														
15. SAFETY: Construction														
Operational														
Accidents														

	LABORATORY WORK	* STORAGE	PROCEDURES	* LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	* TESTING	OPERATION AND MAINTENANCE	* WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
SIGNIFICANT	—		—		—				—	—
MINOR	—		—		—				—	—

Figure A6-19

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APPENDIX M
SUMMARY OF NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM MONITORING REPORTS FOR CONNAUGHT LABORATORIES, INC. FOR THE PERIOD MAY 1990 THROUGH MAY 1992

NPDES COMPLIANCE RECORD FOR THE CONNAUGHT LABORATORIES WASTEWATER TREATMENT PLANT

Month	Parameter						
	BOD	TSS	Ammonia	COD	Fecal Coliform Bacteria	Cyanide	pH
May (1990)	X						
June	ND	ND	ND	ND	ND	ND	ND
July	X	X					
August	X	X					
September							
October	X						
November	X						
December	X						
January (1991)	X						
February	X	X					
March	X	X					
April	X						
May							X
June							X
July							
August					X		X
September		X					
October							
November							X
December		X	X				
January (1992)		X	X				
February		X					
March							
April							
May							

An X denotes when a parameter exceeded permitting requirements. "ND" indicates that no data were available for the time period. BOD=Biological Oxygen Demand, TSS=Total Suspended Solids, COD=Chemical Oxygen Demand. (Data compiled from the files of the PADER and Kilby, 1992b)

CONCENTRATIONS OF COPPER, LEAD AND MERCURY IN THE EFFLUENT FROM THE CONNAUGHT LABORATORIES WASTEWATER TREATMENT PLANT

DATE	Copper	Lead	Mercury
	Concentration in parts per billion (ppb)		
May (1990)	60	<20	0.8
July	<30	<20	1.2
August	60	30	1.6
September	60	<20	0.9
October	160	<20	1.5
November	90	30	1.2
December	140	20	1.5
January (1991)	50	20	1.3
February	170	40	1.5
March	90	5	8.0
April	105	4	0.6
May	132	6	1.0
June	100	3	2.1
July	120	5	1.4
August	192	9	3.9
September	183	12	3.4
October	174	17	1.8
November	225	5	1.8
December	203	11	6.7
January (1992)	205	14	10.1
February	130	10	4.8
March	68	3	2.2
April	35	3	1.1
May	53	3	0.7

(Data compiled from the files of the PADER and Kilby, 1992b)

APPENDIX N
DRAFT EA PUBLIC INVOLVEMENT

DRAFT EA PUBLIC INVOLVEMENT

I. Recipients of the Notice of Availability (NOA) and EA Executive Summary

Joseph W. Battisto
Central Pocono Ambulance Building
Route 611
Tannersville, PA 18372

Ron Bouchard
The Pocono Record
511 Lenox Street
Stroudsburg, PA 18360

John M. R. Bull
The Patriot News
P.O. Box 2265
Harrisburg, PA 17105

James E. Gilbert, President
East Stroudsburg University
Reibman Building
East Stroudsburg, PA 18301

The Honorable John Glenn
503 Hart Senate Office Building
Washington, DC 20510

The Senate Oversight Subcommittee
The Honorable Carl Levin, Chairman
Room 442, Hart Senate Office Building
Washington, DC 20510

Ken Marshall
The Patriot News
P.O. Box 2265
Harrisburg, PA 17105

The Honorable Joseph M. McDade
2370 Rayburn House Office Building
Washington, DC 20515

James J. Rhoades
32 E. Centre Street
Mahanoy City, PA 17948

Rev. Thomas Richards
St. Paul's Lutheran Church
P.O. Box 196
Tannersville, PA 18372

Thomas Slencamp
U.S. Environmental Protection Agency
841 Chestnut Building (3E543)
Philadelphia, PA 19107

The Honorable Arlen Specter
331 Hart Senate Office Building
Washington, DC 20510

The Honorable Harris Wofford
283 Russell Senate Office Building
Washington, DC 20510

Joseph Yannuzzi, Principal
Pocono Mountain High School
P.O. Box 200
Swiftwater, PA 18370

Rev. Henry Zapotocki
Our Lady of Victory Catholic Church
P.O. Box 195
Tannersville, PA 18372

Office of the Governor
225 Main Capital
Harrisburg, PA 17120
Pennsylvania Department of Environmental Resources
P.O. Box 2063
Harrisburg, PA 17105-2063

Department of Transportation
1200 Transportation and Safety Building
Harrisburg, PA 17120

II. Recipients of the NOA and Draft EA

Gerald Bruns
Connaught Laboratories, Inc.
P.O. Box 187
Swiftwater, PA 18370

Jan DePue
Pocono Township Zoning Officer
P.O. Box 197
Tannersville, PA 18372

William J. Manner, Sanitarian Supervisor
Bureau of Community Environmental Resources
480 Clearview Lane
Stroudsburg, PA 18360

Jeremy Rifkin
Foundation on Economic Trends
1130 17th Street, NW
Suite 630
Washington, DC 20036

L Patrick Ross, Chairman
Pocono Township Supervisor
P.O. Box 197
Tannersville, PA 18372

John Woodling, Director
Monroe County Planning Commission
County Courthouse
Courthouse Square
Stroudsburg, PA 18360

III. Those receiving the Draft EA by request

Ms. Elise Bean
The Senate Oversight Subcommittee
Carl Levin, Chairman
Room 442, Hart Senate Office Building
Washington, DC 20510

Mr. John Childe
1389 Bradley Avenue
Hummelstown, Pennsylvania 17036
Dr. Barbara Harper, Toxicologist
Pennsylvania Department of Environmental Resources
P.O. Box 2063
Harrisburg, PA 17105-2063

Lake Swiftwater Club, Inc
P.O. Box 445
Hemyville, PA 18332

Ms. Evelyn U. Lewis
P.O. Box 464
Pocono Pines, PA 19350

Mr. Edward Lee Rogers
Rogers, Goxem, and Krickenberger
1511 K Street, NW, Suite 811
Washington, DC 20005-1401

Nachama Wilker
Council for Responsible Genetics
19 Garden Street
Cambridge, MA 02138-3622

IV. Libraries Receiving the Draft EA:

Monroe County Public Library
Pocono Township Branch
(Attn: Ms. Barbara Keiser)
Township Municipal Building
Route 611
Tannersville, PA 18372

East Shore Library
4501 Ethel Street
Harrisburg, PA 17101

V. Newspapers in which Notices of Availability were published:

The Patriot News
P.O. Box 2265
Harrisburg, PA 17105

The Pocono Record
11 Lenox Street
Stroudsburg, PA 18360

NOTICE OF AVAILABILITY - THE PATRIOT NEWS

(Publication Dates: April 20, 22, and 24, 1992)

NOTICE OF AVAILABILITY
Draft Environmental Assessment
for The Salk Institute
Government Services Division

The United States Army Medical research and Development Command (USAMRDC) announces the availability of a draft Environmental Assessment (EA) of The Salk Institute — Government Services Division (TSI-GSD) for public review and comment. The proposed action and subject of the EA is the continuation of work, under USAMRDC contract, at TSI-GSD located on Route 611 in Swiftwater, Pennsylvania. The Salk Institute is a secondary site of the Department of Defense's Biological Defense Research Program and conducts biomedical development and production involving organisms and toxins, some of which require the use of special containment facilities. Activities conducted at TSI-GSD are funded under contract from the USAMRDC for development and production of vaccines and related operations. USAMRDC programs supporting TSI-GSD are authorized and funded by the U.S. Congress, and implemented by the Department of the Army as lead agency for he Department of Defense, to provide U.S. troops with medical protection against potential biological warfare threats and high hazard infectious diseases. the EA is tiered to the Biological Defense Research Program's Final Programmatic Environmental Impact Statement, April 1989 (Record of Decision, November 1989). Impacts discussed in the EA are not considered to have any significant adverse effects upon the quality of the environment.

The draft EA for TSI-GSD is available for public review and comment. Copies are available at the Pocono Branch of the Monroe County Library, Route 17 and Warner Road, Tannersville; and the Dauphin County Library, 101 Walnut Street, Harrisburg. A copy of the document may be obtained by writing to: Commander, U.S. Army Medical Materiel Development Activity, ATTN: SGRD-UMB (Dr. COle), Fort Detrick, Frederick, MD 21702-5009. Written comments should be submitted to the same address. Written comments for consideration in preparing the final EA must be received no later than May 22, 1992.

ERRATUM

The United States Army Medical Research and Development Command (USAMRDC) announced the availability of a draft Environmental Assessment (EA) of The Salk Institute — Government Services Division (TSI-GSD) for public review and comment in this column on April 20. Written comments for consideration in preparing the final EA must be received no later than May 22, 1992 (not May 20, 1992 as stated in the notice). USAMRDC regrets any inconvenience this error may have caused.

NOTICE OF AVAILABILITY - THE POCONO RECORD
(Publication Dates: April 20, 22, and 24, 1992)

NOTICE OF AVAILABILITY
Draft Environmental Assessment
For The Salk Institute
Government Services Division

THE UNITED STATES ARMY Medical Research and Development Command (USAMRDC) announces the availability of a draft Environmental Assessment (EA) of The Salk Institute - Government Services Division (TSI-GSD) for public review and comment. The proposed action and subject of the EA is the continuation of work, under USAMRDC contract, at TSI-GSD located on Route 611 in Swiftwater, Pennsylvania. The Salk Institute is a secondary site of the Department of Defense's Biological Defense Research Program and conducts biomedical development and production involving organisms and toxins, some of which require the use of special containment facilities. Activities conducted at TSI-GSD are funded under contract from the USAMRDC for development and production of vaccines and related operations. USAMRDC programs supporting TSI-GSD are authorized and funded by the U.S. Congress, and implemented by the Department of the Army as lead agency for the Department of Defense, to provide U.S. troops with medical protection against potential biological warfare threats and high hazard infectious diseases. The EA is tiered to the Biological Defense Research Program's Final Programmatic Environmental Impact Statement, April 1989 (Record of Decision, November 1989). Impacts discussed in the EA are not considered to have any significant adverse effects upon the quality of the environment.

The draft EA for TSI-GSD is available for public review and comment. Copies are available at the Pocono Branch of the Monroe County Library, Route 17 and Warner Road, Tannersville; and the Dauphin County Library, 101 Walnut Street, Harrisburg. A copy of the document may be obtained by writing to: Commander, U.S. Army Medical Materiel Development Activity, ATTN: SGRD-UMB (Dr. Cole), Fort Detrick, Frederick, MD 21702-5009. Written comments should be submitted to the same address. Written comments for consideration in preparing the final EA must be received no later than May 22, 1992.

P — April 20, 22, 24

ERRATUM

E UNITED STATES ARMY ..ical Research and Development Command (USAMRDC) announced the availability of a draft Environmental Assessment (EA) of The Salk Institute Government Services Division (TSI-GSD) for public review and comment in this column on April 20. Written comments for consideration in preparing the final EA must be received no later than May 22, 1992 (not May 20, 1992 as stated in the notice). USAMRDC regrets any inconvenience this error may have caused.

P — April 27, 29; May 1

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APPENDIX O
PUBLIC COMMENTS ON THE DRAFT EA AND RESPONSES TO THE COMMENTS

EAST STROUDSBURG UNIVERSITY EAST STROUDSBURG, PA 18301-2999

Office of Administration and Finance — (717) 424-3201

May 11, 1992

Commander
U.S. Army Medical Material Development Activity
ATTN: SGRD-UMB (Dr. Cole)
Fort Detrick
Frederick, Maryland 21702-5009

Dear Dr. Cole:

Dr. James E. Gilbert, President, East Stroudsburg University of Pennsylvania, has asked that I respond to your letter dated April 21, 1992 concerning the Draft Environmental Assessment for the Salk Institute - Government Services Division, located in Swiftwater, Pennsylvania.

The limits of time do not permit a thorough review of the Draft Environmental Assessment, therefore, I am submitting a "no comment" response.

Sincerely,

Curtis R. English

Curtis R. English, Ed.D.
Vice President for
Finance and Administration

CRE/sw

pc: Dr. James E. Gilbert

RECEIVED 15 MAY 1992
RKF

Responses to Comments from Curtis R. English, East Stroudsburg University (#1)

No response

EVELYN U. LEWIS, M.S.
COUNSELOR
Specializing in Geriatrics
P.O. Box 464
POCONO PINES, PA 19350
717/646-4113

May 18, 1992

Dear Francis E. Cole, Jr., Ph. D.

I have read The Salk Institute Government Services Division (TSI-GSD) Environmental Assessment (Draft).I am glad that I have been given the opportunity to comment on this draft. I do not have any criticism of this manual, and I have no input as to the working of the Salk Institute.

One of my assignments in working for the United States Secret Service was to occasionally enter the facility, enter an application for emplyment inorder to see if I would be needed especially in their security system. I did just that until 1985 when I moved from Cress-Rose Cottages to Pocono Pines.

I am no longer around tbe corner from the laboratory. I do drive by their front door. I have started to attend some school board meetings which was also a directive by the Secret Service. The school board office is across the road from the laboratory.

I can follow any directives that would be vital to the United States Army. Thank you for sending me this Draft.

Sincerly yours,

Sarah Evelyn Lewis

Sarah Evelyn Lewis

NOTARIAL SEAL
SARAH EVELYN LEWIS, NOTARY PUBLIC
TOBYHANNA TWSP., MONROE COUNTY, PA
MY COMMISSION EXPIRES SEPT. 9th, 1995

received
20 MAY 92
Lawrence Lightner

Responses to Comments from Evelyn U. Lewis (#2)

No response

MONROE
COUNTY
PLANNING
COMMISSION

MONROE COUNTY COURTHOUSE
STROUDSBURG, PA 18360
TELEPHONE 717-424-5100

May 19, 1992

Commander
U.S. Army Medical Materiel Development Activity
ATTN: SGRD-UMB (Dr. Cole)
Fort Detrick
Frederick, MD 21702-5009

Re: Government Services Division
Environmental Assessment (Draft)
The Salk Institute

Dear Dr. Cole:

The above cited Environmental Assessment was reviewed by Lisa Surma, Environmental Planner, on behalf of the Monroe County Planning Commission.

These comments are subject to action by the Monroe County Planning Commission at its regular meeting on June 9, 1992 at 7:00 p.m. at the Monroe County Courthouse. If these comments are not amended and are found to be acceptable by the Board at the June meeting, they should be considered to be approved as enclosed.

We appreciate the opportunity to review and comment on this Environmental Assessment. If you have any questions or require additional comments, please contact me.

Sincerely yours,

John Woodling

John Woodling
Planning Director

JW/jc
Attachment

Rec'd
27 May 92
EAB

MONROE COUNTY COURTHOUSE
STROUDSBURG, PA 18360
TELEPHONE 717-424-5100

TO: John WOODLING, Planning Director

FROM: Lisa Suma, Environmental Planner

DATE: May 19, 1992

SUBJECT: The Salk Institute, Government Services Division
Environmental Assessment (Draft)

The Salk Institute - Government Services Division (TSI-GSD) Environmental Assessment (Draft) as prepared by the U.S. Army Medical Materiel Development Activity has been submitted to this office for comment._

The work that is done at TSI consists mainly of vaccine production under contract with the United States Army Medical Research and Development Command (USAMRDC). The assessment report addresses the environmental, social and economic impact that TSI activities have.

The report also outlines safety and emergency procedures that are established at TSI.

The above mentioned report has been reviewed and the following comments are offered:

1. There are several areas in the report where updated census information would best be utilized (Section 4.1.13.3):

Monroe County Housing Units 1980	37,222
Monroe County Housing Units 1990	54,823

2. Swiftwater Creek is classified as High Quality-Cold Water Fishery (HQ-CWF) by the Commonwealth of Pennsylvania, not Highest Quality as referred to in the report (Section 5.2.1).

3. As a part of the Monroe County Water Quality Studies, volume of flow (cfs) is measured at each site. There are several sites on the Swiftwater Creek in the vicinity of Connaught Laboratories/The Salk Institute (Section 5.2.1) which include the following:

   1990, 1991 - 20 yards downstream of Connaught Laboratories discharge
   1990, 1989, 1988, 1985 - 100 yards downstream of bridge on Lower Swiftwater Road (downstream of Connaught Labs)
   1991, 1990, 1988 - 20 yards downstream of old covered bridge at the Swiftwater Inn, west of Route 611 (upstream of Connaught Labs)

4. The Grand Central Sanitation (GCS) landfill is located in Northampton County, not Hampton County (Section 5.2.2).

This review is subject to approval by the Monroe County Planning Commission at their next regularly scheduled meeting.

LS/jc

Responses to Comments from the Monroe County Planning Commission (#3)

3-1 These updated census data have been incorporated into the revised EA.

3-2 Typographical error corrected in the revised EA.

3-3 The Monroe County Studies you have cited were evaluated during the preparation of the EA However, given the large seasonal component in water flow in Swiftwater Creek, these data were viewed to be insufficient (measurements 2-3 times per year) to establish flow regimes for the creek In the context of the EA flow patterns in Swiftwater Creek are important parameters to determine the degree to which discharge from Connaught Laboratories wastewater treatment plant would be diluted. The existence of these limited data have been incorporated into the revised EA.

3-4 This omission has been corrected in the revised EA.

LAKE SWIFTWATER CLUB, INC.
P.O. Box 445
Henryville, PA 18332

May 21, 1992

Commander
U.S. Army Medical Material Development Activity
ATTN: SGRD-UMB (Dr. Francis Cole)
Fort Detrick Md 21702-5009

Dear Dr. Cole,

I am writing in reference to your d a ft environmental impact statement regarding operations at The Salk Institute Government Services Division in Swiftwater, PA. I have studied the copy of that statement available at our local library but would appreciate it if you would send us a copy for future reference.

Our corporation owns an approximately 20 acre lake impoundment on the Swiftwater Creek about 2 1/2 miles downstream from your operations. Built in the 1920's, this lake has been owned and used for swimming, fishing, boating and wildlife preservation by many of the same 25 families from its beginning until now. It is the place where sediments from any disturbances upstream settle out. It is also subject to the possibility of pollution from any malfunctioning sewage system upstream. A chart -term incident of that nature may pass through the stream quickly, but has a longer term impact on our lake because water is retained there.

As you note in your report the Swiftwater Creek, including our lake, is classified as a "high quality cold water fishery" by the State of Pennsylvania. Uncontrolled land disturbances and malfunctioning sewage systems impacting the stream are not permitted under this designation. Nevertheless, they do take place from time to time. We are, of course, concerned about the effect of such events on the historic uses of our Lake, which represents a considerable property investment for the families involved, while also serving the community by providing wildlife protection, green space and flood control.

In addition to our private interest, we are all citizens of this community, with a natural concern for its safety and welfare.

Having indicated our standing to comment on your report, we would like to comment on the report itself. We don't feel that there are any current out- issues between us and The Salk Institute. They have been good neighbors, and we appreciate their helpfulness in getting this statement to you. There are, however, a number of areas of general concern which we wish to raise and hope will be addressed in your final environmental impact statement. (We would appreciate a copy of that, too, when available.)

First, it appears to us that the authors of the report did not spend enough time examining the specific environment of the Swiftwater region. Other than references to development along Route 611, they tended to confine themselves to generalities about Monroe County. Our lake is not mentioned, although it is the primary recipient of sewage discharge from the Salk Institute through their use of the Connaught Laboratories treatment plant. The existence of a growing public school complex just half a mile away, which will serve 3000 students by the fall of 1993, seems to get insufficient attention under safety concerns.

This lack of emphasis on particular local conditions is illustrated in the statement's narrative treatment of our larger fauna. The lead paragraph lists only game species of mammals and birds out of the 257 species found in our region. Two of the nine listed - the ring-necked pheasant and bobwhite - are really only found in this part of the county as escapees from breeding farms. Our understanding is that an environmental impact statement should be concerned with the health of all wildlife in a region, not just those animals which are used by man.

We have a particular concern in this area, because our lake has been home to ospreys, classified as Pennsylvania endangered, and otters, classified as Pennsylvania special concern. Ospreys have used the lake every year and nested there Last summer. Otters have been using the creek and lake sporadically for the past 8-10 years. You should be aware that award-winning programs to study, re-introduce and protect both species in this general area have been underway for many years, under the leadership of Dr. Larry Rymon at East Stroudsburg University. Both the otter and the osprey are at the top of the fish-eating foodchain, so our water quality, as affected by effluents, is key to their success here.

That brings us to the question of water quality and the impact of the Connaught treatment plant on our lake and stream. Over the years, there have been a number of malfunctions at that plant. As recently as last fall, a bulldozing accident led to the discharge of 30,000 gallons of highly chlorinated water into the creek. Although they replaced the fish that were killed as a 5 result, they were not able to replace all the lower organisms that were also destroyed and are essential to the health of a trout stream. In addition, they have frequently exceeded the limits on some aspects of their sewage discharge. For these two reasons, they recently paid a $13,800 civil penalty.

In addition to these recent matters and various hearsay records of their problems over the years, our files-from 30 years ago document a substantial fuel oil leak from the laboratory, again caused by a careless bulldozer operator, which led to environmental problems and a civil penalty.

As names like Three Mile Island, Bhopal, Chernobyl and Exxon Valdez remind us, any system designed and run by humans is subject to the danger of malfunction through human error. Considering the toxicity of substances being used and stored at The Salk Institute, and their reliance on Connaught's sewage treatment plant, Connaught's safety record is a significant cause for concern on our part.

We would particularly point out that last fall's chlorine spill took place on a Saturday, but wasn't discovered until Monday, because there is no weekend monitoring of the plant. Again, considering the hazardous substances involved, we believe the Swiftwater community has the right to demand 24 hour monitoring.

It also appears to us that the draft statement is somewhat too optimistic in assessing accidental dangers to the Salk plant. We can think of four plausible scenarios which would breach Salk's security. Monroe County has experienced light crashes and a devastating chemical truck explosion, and many in our community remember the 500 year flood of 1955 when most man-made systems were stressed beyond their design capabilities and failed. In this day and age the possibility also exists of terroristic direct action by animal rights activists, aimed at either laboratory.

Any of the events imagined in the last paragraph might release Pathogens into the atmosphere. Those related to tropical diseases might not thrive here but at least one, tuleremia, has an active host population of rabbits to be a cause for concern.

The question of accidental release also involves an assessment of the risks involved with rodents and arthropods, who have a long world-wide history of penetrating the best human defenses. All of these possibilities, however remote seem of special concern because of the proximity of 3000 school students.

It appears to us that the Salk Institute has tried to maintain a very low profile about its operations. Their public statements about their activities have tended to stick to soothing generalities. For example, in response to our question about their products in 1985, Dr. French, the Director, responded that they manufacture "biologicals, principally bacterial and viral vaccines, under contract to an agency of the U.S. Government". The fact, of course, which is not hidden in your statement, is that the Salk Institute is one of just three primary sites in the whole country for research in germ warfare.

If they were manufacturing and stocking offensive weapons, that would raise many questions about the appropriateness of this activity he-e - or anywhere else, for that matter. But your impact statement makes it clear that this is not the case. There is certainly a national and humanitarian value in their work in constructing defenses against such diseases, whether found in nature or used as weapons.

We assume that Salk's low profile is based on a desire to avoid uninformed or misinformed confrontations. We suggest a review of that policy, for two reasons. The first is that, in spite of their low profile, rumors about their activities abound. It seems to us that it would reassure the community to know -their real mission, stripped of euphemisms. The more important reason is the possibility of accident or human error noted above. In the event that toxic material might be liberated into the environment, it would be important for the medical community and emergency workers to know what to expect and for neighbors like the school and our lake community to be alerted and have a plan of action. We are required to have such a plan against the unlikely failure of our dam. Surely the federal government, which requires this of us, can do no less for facilities it supports.

In regard to the last paragraph, waiting for an actual disaster to take place is too late: a civil defense plan is needed now, taking everyone concerned into your confidence and establishing their roles in the event of a problem.

Finally, it seems to us that the relationship of m e Salk Institute and its environment needs to be a subject of continual review, as this area keeps growing at a rapid pace. As years go by, the odds increase that human error or natural catastrophe may cause an accident affecting many more people than would have been the case 30 or even ten years ago. Somewhere down the line, it would seem appropriate to plan to use a more isolated facility.

One additional thought on the relationship with Connaught's sewage treatment plant. Your statement mentions the existence in your effluent of certain substances, like heavy metals, for which the Pennsylvania Department of Environmental resources does not hold you to a standard. Still, they impact on our water quality. This is particularly true of phosphates, which can destroy a lake. There is a good deal of local interest in voluntary adoption of stricter standards, like those proposed by the Delaware River Basin Commission, which would have less negative impact on the local environment. We would strongly urge Salk and Connaught to become part of this process.

Again, we wish to underline the point that we do not feel that Salk is or has been a bad neighbor. The concerns expressed here are simply inevitably posed by the nature of their operations. we hope they will be addressed in your final statement. We also hope that you will adopt the specific policy recommendations of 24 hour monitoring and upgraded standards for the Connaught sewage treatment plant, and a civil defense plan for possible failure of safety precautions at Salk. We would also like future assessments of environmental impact to be aware of local wildlife issues and affected organizations, like the Pocono Mountain School District and the Lake Swiftwater Club, Inc.

Again we thank those at Salk who have helped us Communicate these concerns to you. We trust that we can work well with them to preserve our local environment. Thank you for your attention to these concerns.

Sincerely,

Peter Salmon
President

Copies to:

Paradise Township Supervisors
Pocono Township Supervisors
Pocono Mountain School District
Brodhead Protective Association
Swiftwater Preserve
Connaught Laboratories
The Salk Institute

Responses to Comments from the Lake Swiftwater Club, Inc. (#4)

4-1 Consistent with the National Environmental Policy Act (NEPA), the purpose of Section 4.0 is to describe the general environmental setting of TSI-GSD. Where available and appropriate, site-specific data have been included and emphasis has been provided on those environmental components most likely to be impacted by TSI-GSD activities. However, in response to this expression of concern both the school and the lake have been incorporated into the description of the environmental setting (see Section 4.1).

4-2 The description of the wildlife of the region provided in the EA is appropriate given the lack of significant impacts of TSI-GSD operations on this environmental component (see Comment 4-1). Moreover, there are no site-specific data describing the wildlife in the region around TSI-GSD (see Section 4.1.2 and 5.2.4).

4-3 This assessment of operations of TSI-GSD did not identify any significant adverse impacts resulting from the routine operations, including to Swiftwater Lake, or to species, to include otters and ospreys, that frequent the Lake (see Section 5.2.1 and 5.2.4).

4-4 A description of the chlorine accident at the Connaught laboratories wastewater treatment plant has been provided in the revised EA (see Section 5.3). This incident is clearly an isolated event. Connaught Laboratories no longer uses chlorine in the wastewater treatment plant. Therefore, there is no chance such an event will re-occur. Moreover, the accident was not a direct result of the activities of TSI-GSD.

4-5 As mentioned in the revised EA, an electrofishing survey of Swiftwater Creek was conducted in June 1992 (see Section 5.2.1). This study indicated the presence of numerous young of the year fish. The presence of such fish implies the lower portion of the food chain is re-established and no lasting impacts to the Creek resulted because of the chlorine accident (see Comment 4-4).

4-6 There is no evidence that the past problems of the Connaught Laboratories wastewater treatment plant have affected water quality of Swiftwater Creek or downstream locations, including Swiftwater Lake. In addition, recent upgrades to the wastewater treatment plant have brought these operations into compliance with the NPDES standards (see Section 5.2.1 and Section 5.2.4, Comment 4-4 and Comment 4-5).

4-7 Fuel oil at TSI-GSD is currently stored underground in steel tanks lined with epoxy-fiberglass. These tanks are embedded in an excavated hole which was blasted out of bedrock. The tanks are equipped with certified gauges and are pressure tested twice a year. Tank volumes are measured and recorded daily. Therefore, there is minimal probability of such an accident occurring given the current storage practices and safeguards utilized for fuel oil (see Section 2.3.2.5).

4-8 Surveillance of TSI-GSD grounds is conducted on a 24-hour a day basis (see Section 2.3.1). The chlorine accident occurred on Connaught Laboratories property.

4-9 These scenarios were not considered credible events. The programmatic evaluation of the BDRP and the site-specific evaluation of TSI-GSD provided no evidence that such unlikely events would produce adverse impacts to the environment because the quantity of biological materials handled at TSI-GSD is extremely small and because of the effective implementation of other safeguards (see Section 5.3.2).

4-10 It is true that cottontail rabbits are a reservoir for Tularemia (see Appendix 7, BDRP FPEIS). Based upon the small quantity of Tularemia in use at TSI-GSD catastrophic events such as those described in your comment, and evaluated in the BDRP FPEIS, would not result in a significant increase in the reservoir of this disease in the area around Swiftwater (see Comment 4-6).

4-11 Building design features and safety/health procedures used at TSI-GSD are consistent with CDC/NIH guidelines for organisms requiring BL-3 containment. There have been no releases of infected rodents or arthropods from TSI-GSD or other similar BDRP facilities resulting in infection to members of the public or permanent entry into the physical environment (see Sections 5.2.5.1, 5.2.5.2, 5.3.1, and 5.3.2).

4-12 The work performed at TSI-GSD involves production of vaccines and diagnostic reagents (see Section 1.1). TSI-GSD does not, and has never, engaged in the research or storage of biological weapons (see Section 5.2.6).

4-13 TSI-GSD has prepared the *Preparedness Prevention and Contingency Plan, The Salk Institute Government Services Division* which describes procedures to be followed and officials to be notified in the event of a major accident or emergency (see Section 2.3.3.3).

4-14 This option was addressed as Alternative I in the EA (see Sections 3.2 and 5.5.1). There is no evidence that routine operations of TSI-GSD will cause significant negative impacts to the environment (see Comment 4-3, Comment 4-4, Comment 4-5, Comment 4-6, and Comment 4-7), specifically the health and safety of the general public (see Section 5.2.5.1).

4-15 Potential minor impacts to water bodies downstream from the Connaught Laboratories wastewater treatment plant discharge are discussed in the revised EA (see Sections 5.2.1, 5.2.4, and 5.4). These effects are minor. Currently, Connaught Laboratories is voluntarily reducing the metal concentrations in the effluent from its wastewater treatment plant before the new NPDES standards go into effect in 1994 (see Sections 2.3.2.2, 4.1.1, and 5.2.1). The phosphorus concentrations in the effluent of the Connaught Laboratories wastewater treatment plant exert a minor negative impact on the water quality of Swiftwater Lake. However, given the flow-through nature of this system any negative impact of phosphorus would be both minor and transitory (see Wetzel, 1975).